FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR

A THESIS SUBMITTED TO

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT (PUNJAB)

IN THE PARTIAL FULFILLMENT

FOR THE AWARD OF DEGREE OF

MASTER OF SURGERY

IN

ORTHOPAEDICS

MAY 2023

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DEDICATED TO
MY
GRANDFATHER
SR. TASVEER SINGH
SIDHU

ACKNOWLEGEMENT

As I sit down to pen the conclusion to this thesis, memories flash in my mind and fill my heart with immense gratitude towards all those who; with their unending support and encouragement, have contributed in its successful completion and made this an unforgettable experience for me. I am highly grateful to the Almighty for enlightening the path and being the guiding force through all ups and downs in this journey.

I would like to express the deepest appreciation to my supervisor and mentor, ***Dr. Harpal Singh Selhi*** *(Professor, Department of Orthopaedics, DMC&H, Ludhiana), his teachings and guidance have kept me on path and driven me towards my goal. I take great pride in expressing my gratitude to him. He has always been an epitome of excellence for me.*

This thesis would have remained a dream had it not been for the scholarly guidance and constant encouragement of my co-supervisor, Dr. Deepak Jain (Professor, Department of Orthopaedics, DMC&H, Ludhiana) With great reverence and profound pleasure, I acknowledge his help and interest at all stages of this project, which helped in making it a success.

Words do not suffice to express my profound feeling of gratitude and indebtedness to Dr Rajnish Garg (Professor and Head, Department of Orthopedics, Dayanand Medical College and Hospital, Ludhiana).It is my proud privilege to have worked under the guidance of such an eminent teacher.

I convey my sincerest thanks to my teachers Dr Pankaj Mahindra, Dr Shekhar Singhal and Dr. Anubhav Sharma for their constant encouragement and Kind support.

Words fail miserably as I express my gratitude to my parents Sr Dharminderjeet Singh Sidhu and Mrs. Kamal deep Kaur who are my ideal in everything. I am a doctor today because of them for all their love and affection, selflessness, numerous sacrifices, unfaltering attention to my needs and unparalleled determination in striving to make me what I am today.

I owe a big thanks to my seniors specially Dr Khushwinder Singh Maan and my batchmates. Love and big thanks to my SR's and elder brothers Dr Amol Rattan, Dr Gobinder Singh and my brothers for life Dr Sahil Singla, Dr Harshit Gupta and SandhuChak13Z who have been my constant pillars of support and strength each day of my residency. I express my appreciation towards my juniors for their unending support in the completion of my thesis.

I am also thankful to Mrs. Namita, R & D DEPARTMENT for their help in the statistical work and Mr Tarun whose help has shaped this manuscript in to a transcript.

Dr Guryodh Singh Sidhu

ABSTRACT

Introduction: Fractures of tibia are very common in patients with trauma; many of them are open and complex type because of its subcutaneous position. To restore optimum function modern day management is fully focused on thorough wound debridement and tissue protection and stabilization. Ilizarov ring fixator has been used for stabilization in treating infected non-union tibial fractures. Our study is to observe the results of ilizarov ring fixator for infected non-union tibial fractures

Objective: To analyse the functional outcomes in management of infected non-union in fracture tibia by illizarov external fixator

Methods: in this study we retrospectively and prospectively analysed 27 patients treated at Dayanand Medical College And Hospital, Ludhiana from 1 January 2018 and follow up till 30 June 2022 who underwent treatment for infected non-union of the tibia with ilizarov ring fixator system. The results were evaluated according to Association for the Study and Application of the Methods of Ilizarov (ASAMI) criteria.

Results: The functional results were excellent in 25.9%, good in 51.9%, fair in 14.9% and 7.4% were poor. The most common complication found in this study was pin tract infection.

Conclusion: Ilizarov ring fixator still remains an excellent treatment modality for tibial non-union, as it addresses the problems associated with the condition.

Keywords: Infected non-union, Ilizarov fixation, Functional outcome.

LIST OF ABBREVIATIONS

- % PERCENTAGE
- ASAMI ASSOCIATION OF SURGEONS FOR THE APPLICATION AND METHADOLOGY OF ILIZAROV
- CM CENTEMETRE
- CRP C REACTIVE PROTEIN (QUANTITATIVE)
- ESR ERYTHROCYTE SEDIMENTATION RATE
- FBS FASTING BLOOD SUGAR
- HBA1C GLYCOSYLATED HEMOGLOBIN
- IRF ILIZAROV RING FIXATOR
- PPBS POSTPRANDIAL BLOOD SUGAR
- YRS YEARS

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INTRODUCTION

The non-union tibial fracture compromised by infection is a difficult reconstructive problem for the surgeon and is a chronic illness for the patient. The patient already endured multiple hospitalizations, many operative procedures, and prolonged treatment with parenteral antibiotics. Infected non-union of the tibia is not only a source of functional disability but also can lead to economic hardship and loss of self-esteem. Despite improvements in managing this condition, the prevalence of infected non-union of the tibia remains high.

Brinker[1] defined non-union as a fracture that according to the treating doctor, has no possibility of healing without surgical intervention. The Food and drug administration of the USA defines non-union as a fracture that is over nine months old and that has not shown radiographic signs of progression toward healing for three consecutive months.[2] Infected non-union of the tibia is a posttraumatic bony wound[3] and is not equivalent to hematogenous osteomyelitis. In a traumatic bony wound, there is an invasion of bacteria from outside the body. During this process, the local soft tissue and blood supply of bone are compromised, which creates an ideal milieu for bacterial proliferation.[4]

Infected non-union can develop[5] after an open fracture, after a previous open reduction and internal fixation (ORIF), or sequelae to chronic hematogenous osteomyelitis.

Infected non-union of a tibial fracture[3] can be termed as a fracture with exposed bone that has been devoid of vascularized periosteal coverage for more than 6 weeks with purulent drainage, positive bacterial culture from the depths of the wound and histological evidence of necrotic bone containing empty lacunae.

PATHOPHYSIOLOGY OF POSTTRAUMATICOSTEOMYELITIS[6][7][8]

Osteomyelitis is not so frequent complication of trauma-induced open fractures and this is especially true of fractures associated with severe soft tissue injury.

Osteomyelitis is notorious for its tendency to recur, even after years of quiescence.

The stages in the pathophysiology are-

1. Entry of pathogens
2. Establishment of infection
3. Interference in host reaction to infection
4. Damage to the host
5. Persistence of infection.

1. ENTRY OF PATHOGENS

The incidence of osteomyelitis is much higher in open fractures when bacteria have the opportunity to enter the wound directly from the environment. Most wounds associated with open fractures are contaminated at the time of injury. The organisms recovered from the wound initially are environmental bacteria such as bacillus, or skin residents such as coagulase-negative staphylococcus, the bacteria recovered from clinical infections are more likely to be hospital-acquired pathogens such as Staphylococcus aureus or facultative gram-negative bacilli.

2. ESTABLISHING INFECTION

The presence of bacteria in a wound is not sufficient to cause infection. Approximately 60% to 70% of open fractures are contaminated by bacteria, but a much smaller percentage go on to infection. Many factors help in the establishment of infection like damage to the local soft tissue & bone due to which traumatized soft tissue and exposed bone become potential binding sites for bacteria. Staphylococcus aureus, the most common cause of posttraumatic osteomyelitis, has receptors for numerous host proteins including collagen. Other factors like compromised blood supply leading to necrosed tissue acting as a foreign body, implants used for stabilization serving as additional foci for colonization of bacteria, and the instability of fracture also help in the establishment of infection.

Once attached to the host surface, many bacteria can adhere firmly by producing biofilm.[9] [Once the bacteria are firmly attached to the

substrate, the exopolysaccharide polymers proliferate and form additional bonds with the substrate as well as between prokaryotic cells. These eventually coalesce to form a microbial biofilm in which each bacterium has access to suitable nutrients and a useful physiological "rapport" with its neighbors. Under favorable conditions, exponential growth soon establishes an extensive bacteria-laden biofilm]. Biofilm protects bacteria from the action of antibiotics, inhibits phagocytosis, impedes the ingress of antibodies, and impairs lymphocyte and B lymphocyte function.

3. INTERFERENCE IN HOST REACTION TO INFECTION

Trauma has been reported to delay the inflammatory response, depress cell-mediated immunity, and the function of polymorphonuclear leukocytes, including chemotaxis, superoxide production, and microbial killing. The presence of a foreign body at the site of infection, usually in the form of a metallic fixation device or prosthetic implants, can inhibit the efforts of host defense mechanisms. Metals used in these devices stimulate the production of cytokines and impair lymphocyte activity.

4. DAMAGE TO THE HOST

Proteolytic enzymes released by phagocytes also can damage surrounding tissue. Certain bacterial products, such as the leucocidins of staphylococcus, may promote this destructive role of neutrophils. Bone resorption is also a feature of osteomyelitis. Osteopenia and weakened bone may predispose the patient to pathologic fractures. In a scenario of existing fractures, bone resorption may delay or prevent its healing.

5. PERSISTENCE OF INFECTION

Factors contributing to the persistence of infection are local tissue damage, deranged host immune system, fracture instability, formation of biofilm by the infecting organisms and bacteria with surface adherence characteristics (resistant to antimicrobials even in absence of biofilm due to adhesion and to the specific material of the substratum).[10]

Hematological investigations with an elevated leukocyte level,

Westergren erythrocyte sedimentation rate, and C reactive protein can be consistent with ongoing deep bony infection, although they are not necessarily diagnostic. Normal levels can be found even with active drainage in which there is little surrounding cellulitis or systemic involvement. Various other investigations like hbA1c, FBS, and PPBS rule out diabetes mellitus.[11]

Several radiographic features, such as cortical irregularity, periosteal reaction, alteration in normal mineralization, or the presence of a bony sequestrum have been associated with deep bony infection, in the presence of fracture non-union (and especially in association with previously implanted metal internal fixation devices)[12]

The tissue biopsy remains the most convenient and accurate method to identify ongoing deep bony infection, despite all advances in diagnostic imaging & lab evaluation. A bone scan can help to identify a deep bony infection by accumulation at the site of infection.[13][14]

The infected non-union has various classifications and the following are commonly followed:

1. May et al[15] -

Type 1- An intact tibia & fibula that can withstand functional loads.
The skeletal involvement is unicortical & debridement can be done without any threat to skeletal integrity.

Type 2- An intact tibia with bone graft needed for structural support.

Type 3- A tibial defect </= 6cm with intact ipsilateral fibula.

Type 4- A tibial defect > 6cm with intact ipsilateral fibula.
(The defect > 6cm cannot be bridged successfully by autograft alone)

Type 5- A tibial defect > 6cm & no usable fibula.

4. Dror Paley[16]-

A1- Mobile atrophic, Bone loss <1cm

A2- A2.1- Stiff hypertrophic without deformity, bone loss <1cm

A2.2- Stiff hypertrophic with deformity, bone loss <1cm

B1- Osseous defect >1cm, length maintained

B2- Bone loss >1cm, shortening present

B3- Both osseous defect & bone loss with shortening.

C – with infection

RECONSTRUCTION:

The overall goal in the reconstruction of an infected, ununited tibial fracture involves more than control of the infection and includes the creation of a healed, aligned, and drainage-free limb that is functionally better than that which could be achieved by amputation and prosthetic fitting. Several factors must be considered in deciding to reconstruct the bone, including the patient's age, metabolic status, mobility of the foot and ankle, the integrity of the neurovascular structures, and importantly, the patient's motivation. Once the decision has been made to reconstruct, the first step is to eradicate infection through the removal of infected, avascular bone with surrounding compromised soft tissue. The extent of bony and soft tissue debridement is defined by the presence of punctate bleeding margins.

When faced with a skeletal defect and associated bony instability, preserving or regaining functional length and bony alignment must be emphasized. Shortening of the tibia >1.8 cm, varus or valgus deformity >10^{o}, recurvatum of >10°, internal rotation >10°, or external rotation >15° all result in term functional disability. Given that, particularly with more extensive bony defects after debridement, external skeletal fixation has assumed an important role in managing the unstable tibial skeleton.[17][18]

Soft tissue coverage[19] is delayed until the extent of the bony and soft tissue infection has been identified, excised and the base of the wound has become vascular. This is best defined as a wound that will support granulation tissue. The possibilities range from skin graft to free tissue transfer. Several local pedicled muscle and myocutaneous flaps exist around the tibia.[20]

The experience of several authors suggests a high rate of success using microvascular free tissue transfers in the presence of large bony defects that require reconstruction, antibiotic-impregnated methyl methacrylate spacer can be used to fill the dead space, in which later bony reconstruction can be done.[21]

Bony reconstruction can be done by various techniques which are

open cancellous bone grafting-Papineau technique,[22] posterior bone grafting and tibiofibular synostosis,[23] anterior cancellous bone graft beneath a flap, fibula-pro-tibia transfer,[24] vascularized autogenous bone graft, nonvascular autogenous cortical bone grafting, and bone transport.

Various methods like a cast, intramedullary nail, plating, external fixator, and ilizarov ring fixator can be used to treat such fractures but the external fixator is better than the plating osteosynthesis as the rate and extent of complications were lower with external fixation and ilizarov is the method of choice due to the procedure being minimally invasive, maximum axial stability and the patient can mobilize weight bearing with ilizarov ring fixator.

During the application of the ring fixator, the wires are introduced through the bone taking into consideration the topography of vessels, nerves, and tendons. The ilizarov device is a circular external fixator the principal component is a ring with a flat surface with multiple holes, nuts, bolts, wires, rods, slotted cannulated rods, and a rod with a partially threaded shaft. The principle of ilizarov that is slow and steady traction of tissues caused them to become metabolically activated, increasing the proliferative and biosynthetic function. The wire should be introduced through the soft tissue straight to the bone before drilling and similarly after the tip emerges through the opposite cortex, the wire should be driven by hammering on the blunt end to prevent tissue from being caught by the spinning tip.[25] To ensure maximum joint movement of a limb in a circular external fixator the muscle being penetrated should be stretched at the time of transfixion. This means that an adjacent joint must be flexed as the wire passes through the extensor surface of the limb and extended as the same wire traverses the flexor musculature. Adjustments must be made in the skin position before wire insertion. The skin should be displaced away from the fracture site to provide maximum skin for elongation. The use of tensioned 1.5 to 1.8mm Kirschner wire (K-wire) was the key to the rigidity of the system while still providing for axial loading which greatly enhances the chance of union at the site of the non-union and prevents

osteoporosis of immobilization. While securing the wire to the ring, the ring must be fixed to the wire and not the wire to the ring. The stability of the fixator varies with the number, diameter, and tension of the wires and the angle between the wires, the spread of wires approaching 90 degrees, the number of rings, the close positioning of center rings to fracture or non-union site, use of olive (stop) wires.

Tension in the wires may decrease after surgery due to deformation, osteoporosis, and other causes. Periodic re-tensioning of wires may be necessary, especially during compression osteosynthesis.

Distraction osteogenesis-[26][27] The concept of callostasis (callus distraction) or distraction osteogenesis was studied in depth by Professor Ilizarov and his associates by performing animal experiments. Its application in infected non-union was worked out in his institute. His work on this concept led to the use of the ilizarov fixator and its many ensuing modifications in the treatment of difficult non-union. The use of a circular fixator provides multiaxial stability which is important for the promotion of the union of fractures. The ideal rate of distraction osteogenesis was ingeniously worked out and found to yield the best results at 1mm per day in multiple fractions during the day.

Ilizarov also stressed the beneficial effects of weight bearing (load) on regenerate. This is one of the major advantages provided by the stability afforded by the fixator, which is also advantageous for a union as well as preventing osteoporosis associated with immobility. The one other contribution of his work in this field, though of controversial significance, is the technique of corticotomy, which he recommended. He stresses the maintenance of the integrity and continuity of the periosteum and the endosteal blood supply. However, this theory has been countered by various subsequent experiments and observations. The period of delay in distraction is sufficient for the re-establishment of the intramedullary vasculature. Often attempts at corticotomy lead to inadvertent disruption of the periosteum, especially in the posterior portions, and often end as an osteotomy. Some investigators have found no significant difference in the quality of the regenerate following corticotomy and osteotomy

The inventor Prof Gavriel Ilizarov was born on 15 June 1921 in Russia He graduated from medical school in 1944. Without any practical training, he was sent to a war-torn region of Kurgan in north Siberia. Many soldiers had posttraumatic osteomyelitis with non-union of long bones. In 1951, out of sheer necessity, he developed a revolutionary technique and called it a RING FIXATOR. With this fixator, he saved the limbs and lives of many soldiers. Word of his success was largely ignored by the mainstream medical authorities in Russia until in 1967, Valery Brumel, an Olympic champion high-jumper, and the national hero had an infected tibial non-union after a motorcycle accident. Brumel was treated with the ilizarov technique and one year later jumped 2 meters in a high jump competition.

In countries with poor traffic norms, there are a huge number of cases of high-energy trauma. Fractures of the tibia are very common with many of them being open and complex types because of their subcutaneous position and thus delayed union and non-union due to infection are some of the commonly observed complications. The non-union is often associated with infections, shortening, deformity, and poor condition of skin. The deformities are also often complex and may include translation, angulation, and rotation of the components.[28]

The ununited tibial fracture compromised by infection is a difficult reconstructive problem for the surgeon. The treatment modality, outcome, and prognosis are highly dependent on the amount of soft tissue loss and injury, the severity of the injury, degree of communition, fragments displacement, mode of injury, amount of bone loss, and presence of infection.

To restore optimum function modern-day management is fully focused on thorough wound debridement and tissue protection and stabilization. Ilizarov fixator is one of the recommended surgical procedures for stabilization and simultaneously correcting angular deformities.[29]

There is a huge number of cases of infected non-union of fracture tibia all around the world and a huge number of studies on this topic but there is a limited amount of literature on this topic in India. It is a

method of minimally invasive external fixation system using small diameter trans osseous ilizarov wires and pins which are tensioned and fixed to circular rings and rods. Ilizarov ring fixator provides good stable fixation in multidirectional and multiplanes and it facilitates the cyclic micromotion at the fracture site for bone healing.

In infected non-union of the bone, the ilizarov ring fixator allows the surgeon to resect the necrotic bone segment and also be able to achieve stable fixation. Further, bone transport can be implemented to create bone regenerate to fill the gap.

Our study is to observe the results of the ilizarov ring fixator for infected non-united tibial fractures. We have used the ilizarov ring fixator for stabilization in treating infected non-united tibial fractures.

AIMS AND OBJECTIVES

To analyze the functional outcomes in the management of infected non-union in fracture tibia by ilizarov external fixator.

REVIEW OF LITERATURE

The Food and drug administration of the USA defines non-union as – "The fracture that is over 9 months old and that has not shown radiographic signs of progression toward healing for 3 consecutive months" or a fracture is said to have "gone on to non-union" when the normal biologic healing processes cease to the extent that solid healing will not occur without further intervention.[30]

The tibia has been the most common long bone fracture in humans because of its location and open fractures are more common in the tibia than any other bone due to subcutaneous location. Open tibial fractures can develop complications because of infection, and inappropriate mechanical and biological environments.[31]

The non-union of a fracture is classified by various authors using different criteria and the two most commonly used classifications were:

Dror Paley[32]

A1- Mobile atrophic, Bone loss <1cm

A2- A2.1- Stiff hypertrophic without deformity, bone loss <1cm

A2.2- Stiff hypertrophic with deformity, bone loss <1cm

B1- Osseous defect >1cm, length maintained

B2- Bone loss >1cm, shortening present

B3- Both osseous defect & bone loss with shortening.

C: with infection

Gordon & Chiu's (on the severity of underlying bone damage).[33] -

A- Tibial defect & non-union without substantial bone loss
(< 3cm)

B- Tibial defect >3cm with intact fibula

C- Tibial defect >3cm with non-union fibula

The problem of non-union occurs when requirements for fracture healing like stability, bone vascularity, and bone-to-bone contact are severely affected by injury severity, a suboptimal surgical fixation which further gets complicated when there was the presence of active

infection in and around the site of non-union. The presence of infection interferes with the stability and reparative process of bone thus further delays in healing.[30]

Infected non-union has been defined as a state of failure of union and persistence of infection at the fracture site for 6 to 8 months. Infected non-union is most frequently observed in the tibia after an open fracture. Exposed bone devoid of periosteal coverage for more than 6 weeks, purulent discharge, a positive bacteriological culture from the depth of the wound, and histologic evidence of necrotic bone containing empty lacunae are other factors associated with infected non-union.[34]

Infected non-union can develop after an open fracture, after a previous open reduction and internal fixation (ORIF), or as sequelae to chronic hematogenous osteomyelitis.[35] Open fracture remains the most common cause of infected non-union of fractures. The increasing number of infected non-union was observed and partly as a result of increased operative fracture care.

The infected non-union of a fracture is classified by various authors using different criteria and the two most commonly used classifications were:

ASAMI classification of infected non-union:[36]
A-Aseptic non-union without bone defect
A1 Mobile (atrophic/hypo trophic)
A2 Stiff without deformity (hypertrophic)
A3 Stiff with deformity (hypertrophic)
B-Aseptic non-union with bone defect
B1 Length of limb preserved with bone defect
B2 Segment in contact with shortening of limb
B3 Combined shortening with defect
C-Infected non-union

Weiland's[37] (on the extent of infection)-

Type 1- Bone exposed and soft tissue infection present (without osseous infection).

Type 2- Circumferential cortical &endosteal infection present.

Type 3- Circumferential cortical &endosteal infection with segmental bone loss present.

The treatment modality, outcome, and prognosis are highly dependent on the amount of soft tissue loss, the severity of the injury, degree of communition, fragment displacements, mode of injury, and amount of bone loss.[38]

Management is fully focused on thorough wound debridement, and immediate stabilization of bone and tissue protection.

The various modalities with which the fractures were treated were:[39]

- Conservative management with traction or cast
- External fixation
- Interlocking Intramedullary nailing
- Plate Osteosynthesis
- Ilizarov ring fixator
- Combination of the above methods.

Ilizarov Ring Fixator has been gaining acceptance as a primary modality of treatment in treating infected non-union tibial fractures.[40] Ilizarov external fixator was a minimally invasive procedure with thin wires transfixing the bone which were augmented by tapered pins attached to the circular frame. It was a versatile (correction of angulation, axial deformity, bone lengthening, bone transport) system in the hands of a surgeon.

The tension stress effect on the growth and genesis of tissue was

studied by Professor Ilizarov who performed corticotomies and summarized that when the callus is distracted at 0.5mm a day at a frequency of 0.125 mm every 6 hours, osteogenesis overtook the speed of distraction causing premature consolidation. He designed an auto distractor that could distract the callus up to 60 times a day over a 1 mm distance to achieve a uniform and good quality callus. For best clinical results he recommended distraction in 4 installments of 0.25 mm each. A rapid rate of the distraction of 2 mm per day retarded osteogenesis and also caused detrimental changes in the soft tissue surrounding the site of distraction. Elongation by 1 mm per day in 4 equal installments led to more favorable results. This physis-like structure ossifies in both the proximal and distal directions from a central growth zone during distraction. Under ideal conditions of fixation and distraction neo-osteogenesis proceeds directly from marrow tissue without the formation of an intervening cartilaginous layer. In this sense, the growth zone of the distraction regenerate resembles intramembranous ossification.[41]

Professor Ilizarov also described techniques by which commonly associated problems like bone defects, angular deformities, rotational deformities, and limb length discrepancy could be overcome with his ring fixator simultaneously thereby providing a single solution to this multifaceted problem of infected non-union. Probably the most significant but inadequately recognized contribution of the ilizarov system to the problem of non-union associated with infection is the vascular response of the bone and the limb to the distraction osteogenesis. Whether this vascular response of the limb is the cause or the effect of the allostasis is not known, but the benefits of this probably are vital in the fight against infection.

Infected non-unions pose a huge challenge as they are complicated by incapacitating pain, soft tissue problems, deformities, joint problems (contractures, deformities, limited range of motion), motor and sensory dysfunction, and osteopenia. The treatment strategy depends on the

nature of the infection (draining, nondraining-active, nondraining quiescent) [42] and involves both a biological and a mechanical approach. Management of infected non-union of the tibia involved radical debridement with excision of all infected tissue that is soft tissues (e.g., fascia, muscle, abscess cavities, and sinus tracts), necrotic bone, and foreign bodies. The bone gap created after debridement is usually managed by an antibiotic spacer to fill the dead space and deliver antibiotics locally.[43][44] After this, the soft tissue coverage is done either by a rotational soft tissue muscle pedicle flap or by moist dressings by the Papineau technique so that split skin grafting can be performed.[45] Infected non-union may involve different segments of bone. Diaphyseal non-union involves primarily cortical bone, whereas metaphyseal and epiphyseal non-unions largely involve cancellous bone. The presence or absence of intra-articular extension of the non-union should also be evaluated. Once the intramedullary and local infection has been eradicated next stage of treatment is performed which is the fixation of the non-union ends done by ilizarov fixator application and further non-union can be treated by either mono-focal osteogenesis (compression and distraction at the non-union site) or bifocal osteogenesis with compression at the non-union site and adjacent corticotomy.[46]

Following distraction, maturation, and hypertrophy of the bony regenerate occurs during the consolidation phase. Finally, the ilizarov fixator is loosened and the patient mobilized weight bearing and the fixator is removed and the limb is protected in a functional brace until complete consolidation occurs.[47]

The ilizarov is a versatile fixator with a modular design of the apparatus that allows the frame to be custom-built for each patient and the wires to be minimally invasive which reduces the risk of bleeding and no other skin incisions are made.[48] It can promote bony tissue generation and often requires only minimal soft tissue dissection. It can be used in the face of acute or chronic infection and allows for the stabilization of small intraarticular or periarticular bone fragments.[49] It also allows for

simultaneous bony healing and deformity correction and the patient can immediately bear and start early joint mobilization.[50]

There are various disadvantages of ring fixators most common being pin site infection which occurs due to inappropriate pin site care by the patient.[51]

Table 1: Moore and Dahl's classification used to classify pin site infection.

GRADE	CHARACTER
GRADE 0	Pin site is normal other than marginal erythema
GRADE I	Marginal inflammation
GRADE II	Inflamed pin site with serous discharge
GRADE III	Inflamed pin site with purulent discharge
GRADE IV	Osteolysis of near and far cortex
GRADE V	Osteolysis of near and far cortex with sequestrum

The risk of neurological or vascular injury during surgery or distraction remains although the surgical procedure is designed to minimize this type of injury. During limb lengthening, patients who are experiencing extreme pain or who demonstrate signs of vascular compromise may have the amount of daily distraction decreased.[52] Joint deformities may develop. Premature consolidation of the lengthening segment may occur before the desired limb length has been achieved. Application of the ilizarov external fixator in children may lead to behavioral changes like frustration, anger, and fear.

The Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria, a clinical and radiographic evaluating tool, was used for the assessment of the sample:

Table 2: Bone Results

Excellent	Union, no infection, deformity <7 ◦, limb-length discrepancy <2.5 cm
Good	Union + any two of the following: absence of infection, deformity <7 ◦, limb-length discrepancy of <2.5 cm
Fair	Union + only one of the following: absence of infection, deformity <7 ◦, limb-length discrepancy of <2.5 cm
Poor	Non-union/re-fracture/union + infection + deformity >7 ◦ + limb-length discrepancy >2.5 cm

Table 3: Functional results

Excellent	Active, no limp, minimum stiffness (loss of <15◦ knee extension/<15◦ ankle dorsiflexion), no reflex sympathetic dystrophy, insignificant pain
Good	Active with one or two of the following: Limp, stiffness, reflex sympathetic dystrophy, significant pain
Fair	Active with at least three of the following: Limp, stiffness, reflex sympathetic dystrophy, significant pain
Poor	Inactive (unemployment or inability to return to daily activities because of injury)
Failure	Amputation

The summary of published studies reporting results of treatment of infected tibial non-union with ilizarov fixator where the treatment was effective in securing infection-free union in the most difficult cases, with large defects and poor soft tissues:

Sofikul et al, in 2022, studied a total of 61 (n=61) tibial non-union patients treated with the ilizarov fixator who also had an infection. ASAMI score criteria were used to evaluate the outcome. The most

common organism for infection was identified to be Staphylococcus Aureus. ASAMI score rating methodology for bone and function results was used and bone results were excellent in 33, good in 18, fair in 7, poor in 3 and functional results were excellent in 34, good in 21, fair in 5, poor in 1. One patient underwent amputation. Pin tract infections were the most prevalent problem discovered in this research found in 7 patients.[53]

Testa et al, in 2020, studied the ilizarov external fixation technique used for the treatment of long-bone infected non-unions.26 patients with infected tibial non-unions were treated with the ilizarov technique. The Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria, a clinical and radiographic evaluating tool, was used for assessing the sample. According to the ASAMI Functional Scoring System, 10 excellent (38.5%) cases and 12 good (46.1%) values were recorded. According to the ASAMI Radiological System, they were excellent in 16 (61.5%) cases and good in nine (34.6%). Conclusions: Treatment of infected tibial non-unions using the ilizarov technique was effective in bone segment regeneration.[54]

Mankar et al, in 2020, studied a total of 20 patients identified who underwent Ilizarov's procedure for infected non-union tibia. The median age was 43.5 years (range: 7–65 years). The median level of bone defect was 60 mm. In 20 cases, 18 had infected non-union. The median consolidation time was 8 months. During the median follow-up of 2 years, 83.3% (15/18) achieved complete union. The median union time was 11 months. Pin-tract infections were observed in 33.3% (6/18) of the patients. As per ASAMI outcomes, bone results were excellent in 72.2% (13/18), good in 11.1% (2/18), and poor in 16.7% (3/18), and the function results were excellent in 50% (9/18), good in 33.3% (6/18), and poor in 16.7% (3/18).[55]

Parihar et al, in 2019, studied the Functional outcome of performing distraction osteogenesis in cases of infected non-union of the tibia

treated with an ilizarov fixator. The study was done with 27 patients with infected gap non-union of the tibia. The ASAMI-Bone healing score was Excellent or Good in 86% of patients, and the Functional score was Excellent or Good in 89% of patients. The commonest problems were pin tract infection, wire loosening, and angulation of the transported segment.[56]

Hosny et al, in 2019, proposed the use of the ilizarov technique in draining infected non-unions through the following study. A total of 144 cases of draining infected non-union were treated by ilizarov fixator using the corticotomy-first technique. The study included humeral (18 cases), femoral (52 cases), and tibial (74 cases) non-union. The mean age was 44.48 years with 87 males and 57 females. The mean duration of non-union was 28.69 months. After debridement, the combined shortening and non-union gap averaged 5.98 (range 3–10) cm. Evaluation of bone and functional results were done according to the Association for the Study and Application of the Method of Ilizarov (ASAMI) criteria. The follow-up period averaged 51.05 (range 36–72) months. None of the cases developed corticotomy site or distraction gap infection. Union was successfully achieved in 141 cases (97.92%). Non-union persisted in three cases (2.08%) in the distal tibia. Infection was eventually controlled in 138 cases (95.83%). The ilizarov fixator with the corticotomy-first technique was effective in the management of draining infected non-united fractures of long bones.[57]

Fahad et al, in 2019, did this study to analyze the role of ilizarov fixation in infected tibial non-union, as well as to assess bony union and associated functional outcomes. A retrospective review was conducted for a total of fifty-one patients with tibial non-union associated with infection who were treated with the ilizarov fixator. Patient records were reviewed for the union of bone, bone, and functional outcomes and complications. The majority of the patients had excellent scores as per the ASAMI grading system for bone and function results. The most common complication noted was pin-track

infections. At last concluded that the ilizarov external fixator is better suited for infected non-union of the tibia because it can provide a stable mechanical environment, bone transport, correct deformities, and enable weight bearing hence we recommend its use for the same.[58]

Bakhsh et al, in 2019, documented the presence of tibial infected non-union and analyze the management outcome with the ilizarov technique in terms of bone results, functional outcome, bone transport time, external fixation time, external fixation index, and any complications. There were 56 patients. According to ASAMI criteria, bone results were excellent in 37(66%), good in 10(17.85%), fair in 6(10.71%) and poor in 3(5.35%). The functional results were excellent in 37(66%), good in 9(16%), fair in 7(12.5%) and poor in 3(5.35%). ilizarov method beautifully addresses the formidable issue of infected non-union of the tibia with good outcomes in terms of bone healing and infection eradication.[59]

McNally et al, in 2017, proposed a treatment algorithm comprising 4 ilizarov methods in managing infected tibial non-union, using non-union mobility and segmental defect size to govern treatment choice. Seventy-nine patients were treated with 1 of 4 ilizarov protocols. Twenty-six had a new muscle flap at the time of ilizarov surgery, and 25 had pre-existing flaps reused. The primary outcome measure was the absence of recurrent infection. Secondary outcomes included bone union, complications, the Association for the Advancement of Methods of Ilizarov (ASAMI) bone and functional classification scores, and any need for further unplanned surgery. Following the initial ilizarov method alone, the union was achieved in 68 cases (86.1%) and was highest among the mono-focal distraction (96.2%) and bifocal compression/distraction groups (93.8%). Mono-focal compression achieved the lowest union rate (73.7%), significantly lower ASAMI scores, and a refracture rate of 31.6%. Bone transport secured union in 77.8% with a 44.4% unplanned reoperation rate. However, the infection-free union was 100% after further treatment.[60]

Sreeram et al, in 2016, studied the results of the use of this technique for the treatment of infected non-union of long bones and the study of complications encountered during treatment. An observational study was done on case records of 20 patients treated with an ilizarov fixator for infected non-union of long bones. Out of the 20 cases treated with the Ilizarov fixator according to the ASAMI score 19 cases of sound union occurred and 70% had excellent bony results and 50% had excellent functional results.[61]

Meleppuram et al, 2016, studied to evaluate the clinical and functional outcome in the treatment of infected tibial non-union by the Ilizarov method. The authors retrospectively analyzed 42 patients with infected tibial non-union bone loss; shortening and deformity. The results were evaluated according to the Association for the Study and Application of the Methods of Ilizarov (ASAMI) criteria. Pin tract infections were assessed by Moore and Dahl score. Bone results were excellent in 60% of patients (n = 25), good in 15% (n = 6), fair in 25%(n = 11), and poor in none. The functional results were excellent in 55% of patients, good in 30%, fair in 5%, and poor in 10%. The most common complication found in this study was pin tract infection. Ilizarov ring fixator remains an excellent treatment modality for infected tibial non-union.[62]

Sahu et al, in 2016, evaluated the outcome of functional and radiological outcome of a complex non-union shaft of the tibia, treated by an ilizarov ring fixator with compression and distraction osteogenesis. 60 cases of complex non-union shaft of the tibia were included in our study. The functional evaluation was done by using Association for the Study and Application of Methods of Ilizarov (ASAMI) scoring system and bone union with serial radiographs. All patients had a successful union. Every patient had pin tract infections which were successfully treated with oral antibiotics. Using the ASAMI scoring system, we obtained 45 excellent, 10 good, 3 fair, and 2 poor

functional results. The ilizarov technique for complex non-union has a high rate of success in achieving union and eradicating infection, bone loss, and malalignment. Radical debridement is the key step to controlling the bone infection.[63]

Ravichandran et al, in 2016, studied retrospectively the functional and radiological outcome of 21 complex non-union shaft of the tibia, treated by radical debridement, ilizarov ring fixator with compression, and distraction osteogenesis. 21 cases of complex non-union shaft of the tibia were included. Using the ASAMI (Association for the study and application of the methods of Ilizarov) scoring system we obtained 10 excellent, 8 good, 2 fair, and 1 poor functional result. The complications were pin tract infection (90 pins out of 220 pins), pin loosening, skin maceration, and limb edema.[64]

Kumar et al, 2016, selected 30 patients with infected non-union tibia treated using the Ilizarov technique and were evaluated by the ASAMI Criteria. Of 30 patients in the study, an average duration of fixation (treatment) of 6.6 months [range 5-10 months] was noted. There were 9 [30%] excellent, 15 [50%] good, 6 [20%] fair and functional results; 8 [26.6%] excellent, [63.3%] good, and 3 [10%]. Persistent bone infection despite bony union was evident in 5 patients. 10 patients had residual shortening of more than 2.5 cm. There was limb edema in many patients despite fracture union. After treatment, 13 cases had more than seven degrees. A significant limp was seen in 9 patients [30%]. After surgery, in 12 patients [40%] stiffness persisted, with more than 15 degrees of loss of range of movement. 5 patients got reflex sympathetic osteodystrophy or skin changes.[65]

Wani et al, in 2015, studied to evaluate the effectiveness of debridement and application of the ilizarov ring fixator (IRF) in the management of infected tibial non-unions. Twenty-six patients with infected non-unions of the tibia were managed by debridement and resection of the infected portion ± partial fibulectomy and stabilization

by ilizarov ring fixator. Bone segment transport was done in 18 patients who had greater than 2.5 cm bone defect after debridement. Bone grafting was required in three patients to augment union. All fractures united and infection was eradicated. There were 13 excellent, nine good, and four fair. Functional results were excellent in nine, good in 11, fair in five, and poor in one. Pin site inflammation was the most common problem and occurred in 23 (88%) patients. There were no major complications or neurovascular complications.[66]

Khan et al, in 2015, reviewed the outcomes of 24 patients who underwent ilizarov ring fixation for infected non-union of the tibia. Patients were assessed using the Association for the Study and Application of the Method of ilizarov criteria. Patients were followed up for a mean of 11 (range, 8–46) months. Functional outcome was excellent in 8 patients, good in 12, fair in 2, and failure in one, whereas bone union outcome was excellent in 6 patients, good in 14, fair in one, and poor in 2. Complications encountered were pin tract infection (n=5), re-fracture (n=2), soft tissue impingement by ilizarov rings (n=2), recurrence of wound infection (n=1), mal-union (n=1), and mortality (n=1). Ilizarov ring fixation is a viable option for infected non-union of the tibia.[67]

Yin et al, in 2015, did a study to evaluate the effectiveness of the treatment of infected non-union of the tibia and femur by bone transport, and 110 patients were studied. All patients achieved union without any recurrence of infection. according to the association for the study and application of the method of ilizarov (ASAMI) classification, bone results were excellent in 68, good in 28, fair in 12, and poor in 2; functional results were excellent in 37, good in 42, fair in 21, and no poor. the study suggested that ilizarov methods in the treatment of infected non-union of the tibia and femur acquired satisfactory results.[68]

Yin et al, in 2014, studied to evaluate the effectiveness of the treatment

of infected tibial non-union by bone transport using the ilizarov external fixator and retrospectively reviewed 66 patients with infected tibial non-union. All the patients achieved bone union and no recurrence of infection was observed for 18-46 months. According to the Association for the Study and Application of the Method of ilizarov (ASAMI) classification, bone results were excellent in 44, good in 15, fair in 5, and poor in 2; functional results were excellent in 24, good in 26, fair in 10 and no poor. The study concluded that ilizarov methods in the treatment of infected tibial non-union acquired satisfactory results in bone union and function of a limb.[69]

Madhusudan et al, in 2008, studied the ilizarov method in infected tibial non-union in 22 consecutive patients with a follow-up of 13 months. The results were analyzed using the ASAMI scoring system. Of 22 patients in the study, 13 patients who underwent external bone transport, had an average bone gap of 4 cm [2–11 cm] with an average duration of fixation of 9.3 months [6.5–13 months]. There was 4 excellent, 3 good, 4 fair, and 2 poor bony results and 1 excellent, 3 good, 6 fair, and 2 poor results. 1 patient was lost for follow-up at the final functional analysis. 9 patients who underwent internal bone transport had an average bone gap of 5.4 cm [1.5–9 cm] with an average duration of fixation of 8.5 months [4–11 months]. There were 3 good 4 fair and 2 poor bony results and 1 good, 3 fair, and 2 poor functional results. Patients with fair to poor results preferred amputation to limb salvage even though they retained their limbs.[70]

MATERIALS AND METHODS

A retrospective and prospective study was done on patients who underwent treatment for infected nonunion of the tibia with ilizarov ring fixator system. All the patients of infected nonunion tibia admitted in the Dayanand Medical College and Hospital, Ludhiana in the orthopedics department were considered.

Proper history from the patient was taken related to injury and the time lag.

Whether the patient was immunocompromised or not was also documented in the case sheet.

Patient was asked about the presence of any comorbidities or substance abuse (smoking, alcohol).

Cultures were taken whenever there was a discharge from the wound/sinus.

The patients with a discharging sinus at presentation were grouped as having active infection and those with at least 3 months of discharging sinus initially which later became quiescent were grouped as having quiescent infections.

INVESTIGATIONS:

Hematological investigations required were carried out:

- hemogram
- renal function tests
- Erythrocyte sedimentation rate
- C reactive protein(CRP)(quantitative)
- Viral markers(rapid)
- Hba1c, FBS, PPBS (if diabetic)

Radiological:

X-rays full length with the whole tibia with knee and ankle were done in AP and Lateral view were done.

SURGICAL TECHNIQUE:

The patient underwent radical debridement with excision of all infected tissue and if required (if gap present between fracture ends) an antibiotic spacer will be inserted. This is followed by the ilizarov external fixator is applied following the standard protocol.

The second stage started with removal of antibiotic spacer if insitu and corticotomy which was done at initial stage after ilizarov or at the time of antibiotic spacer removal.

After this the bone transport was begun after 10-14 days at the rate of ¾ mm per day maximum of up to 1 mm per day till the docking site is compressed and bone grafting was done if required. The days required for regenerated bone maturation are double the number of days for bone transport. The patient was taught how to do pin site care at home. In a few cases the regeneration was poor, so here we used the Accordion rhythm (alternate compression and distraction) to increase the rate of regeneration.

Finally, we dynamized the patient and loosened the ilizarov fixator and then removed the fixator, and applied a Patella tendon bearing (PTB) cast for 6 months.

ADVANTAGES:

- The modular design of the apparatus allows the frame to be custom-built for each patient.
- The circular nature of the frame both enhances stability and evenly distributes the stress across the corticotomy and the distraction gap.
- The structure and strength of the frame allow weight bearing throughout the treatment, which is beneficial to the patient both in terms of day-to-day mobility and helping to build muscle strength and prevent joint stiffness.[48]
- When the frame is applied to the limb during surgery, only wires fix the bones to the rings, and no other skin incisions are made, which reduces the risk of bleeding, infection, and damage to the

surrounding soft tissues. [49]

- It stabilizes the fragments of bone to promote union when traditional methods of fixation are unable to give proper hold on the fracture fragments. It also allows significant compression in the case of non-unions.[50]

DISADVANTAGES:

- Pin site infection may occur due to inappropriate pin site care by the patient.[51] (Moore and Dahl classification) as per table 1.
- There is a risk of neurological or vascular injury during surgery or distraction, although the surgical procedure is designed to minimize this type of injury. During limb lengthening, patients who are experiencing extreme pain or who demonstrate signs of vascular compromise may have the amount of daily distraction decreased.[52]
- Joint deformities may develop.
- Premature consolidation of the lengthening segment may occur before the desired limb length has been achieved.
- Application of the ilizarov external fixator in children may lead to behavioral changes like frustration, anger, and fear.

SOURCE OF DATA

Retrospective And Prospective Analysis of Functional Outcomes in Management of Infected Non-Union in Fracture Tibia By ilizarov external fixator were Conducted In Patients Undergoing Treatment At Dayanand Medical College, Hospital.

METHOD OF COLLECTION OF DATA

Data was collected as per the proforma with consent from the patients admitted to the Orthopaedic department, Dayanand Medical College, and Hospital.

INCLUSION CRITERIA

- Patients in the age group of above 15-70 years
- Both male and female patients
- Patients with infected non-union in the tibia

EXCLUSION CRITERIA

- Non-union flowing pathological fracture
- Non-union following congenital disorder

Duration of Study: The patients operated at Dayanand Medical College and Hospital, Ludhiana from 1 January 2018, and follow-up till 30 June 2022 were included in the study.

Outcome: In this study, we analyzed the functional outcome of infected non-union of fracture tibia managed with an ilizarov fixator.

Statistical Analysis: Data will be described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases), and relative frequencies (percentages) as appropriate. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

OBSERVATION AND RESULTS

Retrospective and prospective study was done on 27 patients from 1 January 2018 and follow up till 30 June 2022 who underwent treatment for infected non-union of the tibia with ilizarov ring fixator system. All the patients of infected non-union tibia admitted in the Dayanand Medical College and Hospital, Ludhiana in orthopaedics department were considered.

Table 4: Distribution of participants in terms of age (years).

AGE GROUP (years)	No. of cases	Percentage
< 30	7	25.9%
31-40	7	25.9%
41-50	3	11.1%
51-60	3	11.1%
> 60	7	25.9%
Total	27	100.0%

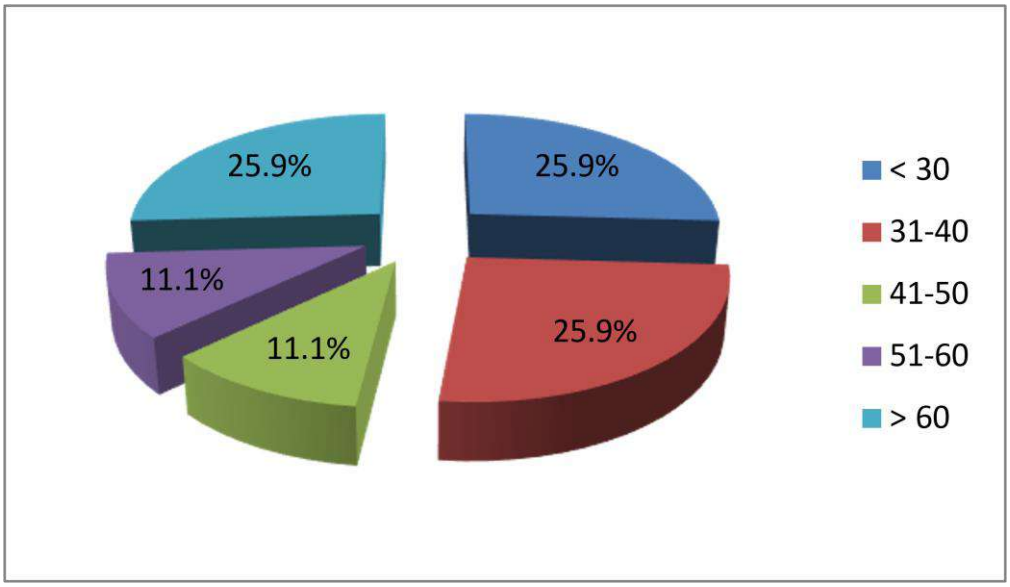

Figure 1: Figure showing a total of 27 patients who were enrolled in this study with mean age of 44.11(years). The age ranged from 15-70 years.

Table 5: Distribution of patients according to gender(n=27).

SEX	No. of cases	Percentage
F	4	14.8%
M	23	85.2%
Total	27	100.0%

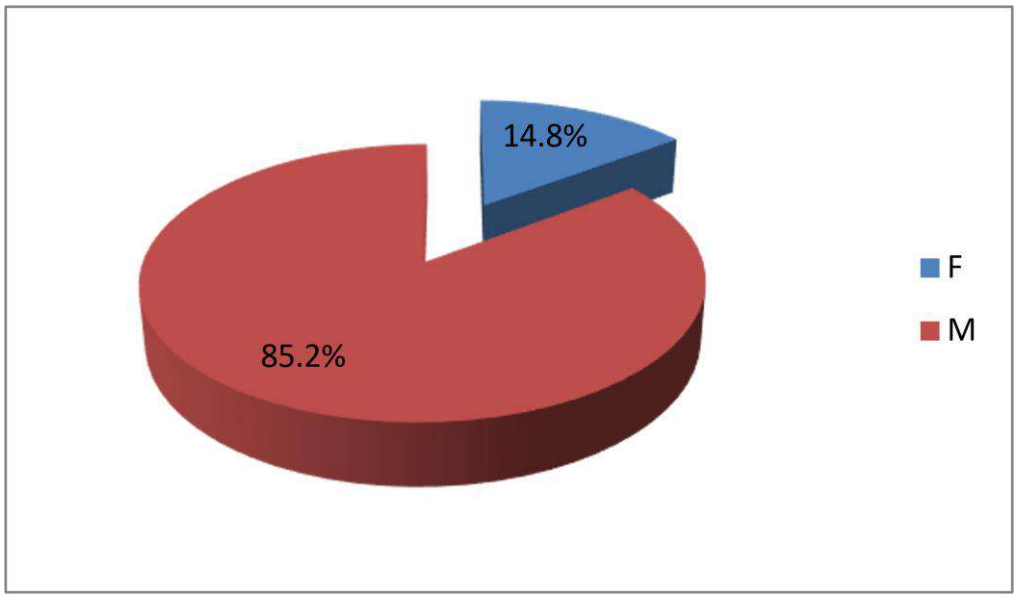

Figure 2: Distribution of patients according to gender (n=27).

In total of 27 patients enrolled in study 23 were male and 4 were females.

Table 6: Distribution of patients according to mode of injury(n=27).

Mode of injury	No. of cases	Percentage
RSA	26	96.3%
WORK PLACE INJURY	1	3.7%
Total	27	100.0%

It shows that 96.2 percent of the patients were injured in road side accidents and 3.8 percent in work place injuries.

Table 7: Showing the site of fracture in tibia with infected non-union in 27 patients.

FRACTURE SITE	No. of cases	Percentage
DISTAL TIBIA	10	37.0%
MID TIBIA	11	40.7%
PROXIMAL AND DISTAL TIBIA (SEGMENTAL)	1	3.7%
PROXIMAL TIBIA	5	18.5%
Total	27	100.0%

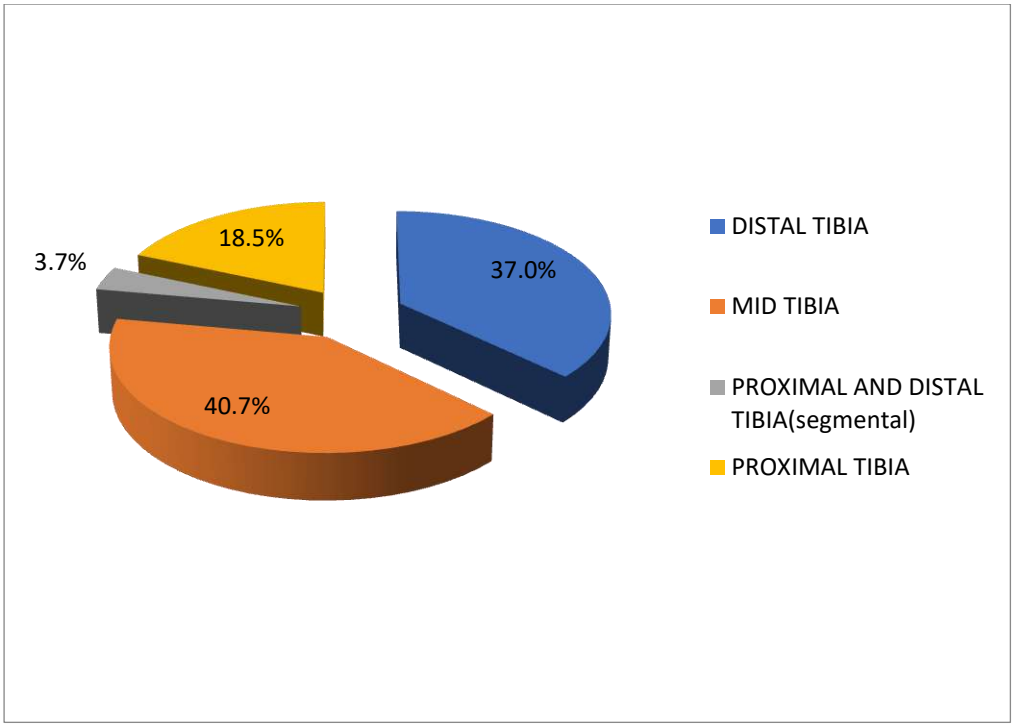

Figure 3: Figure showing different sites of fracture in tibia with infected non-union.

Table 8: Showing different types of microorganisms found after culture examination of sample from the infected site.

CULTURE	No. of cases	Percentage
AEROMONAS HYDROPHILLIA	1	3.7%
CITROBECTOR SPECIES	1	3.7%
E COLI	2	7.4%
ENTEROBECTOR CLOACAE	1	3.7%
KLEBSIELLA PNEUMONAE	3	11.1%
KLEBSIELLA SPECIES	2	7.4%
NO GROWTH	12	44.4%
PSEUDOMONAS SPECIES	2	7.4%
STAPHYLOCOCCOS AUREUS	2	7.4%
STENOTROPHOMONAS	1	3.7%
Total	27	100.0%

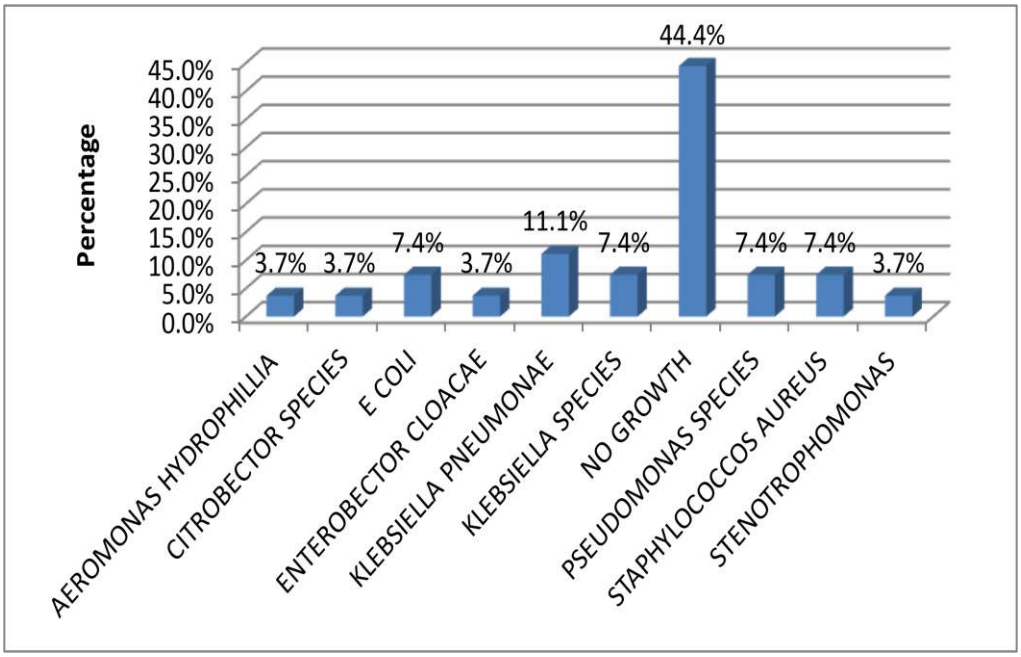

Figure 4: Bar diagram showing microorganisms found after culture examination of sample from the infected site with no growth in samples who were on antibiotics prior to admission.

Table 9: Showing number of additional major procedures performed in patients with infected non-union tibia.

MAJOR	No. of cases	Percentage
0	1	3.7%
1	12	44.4%
2	7	25.9%
3	4	14.8%
4	3	11.1%
Total	27	100.0%

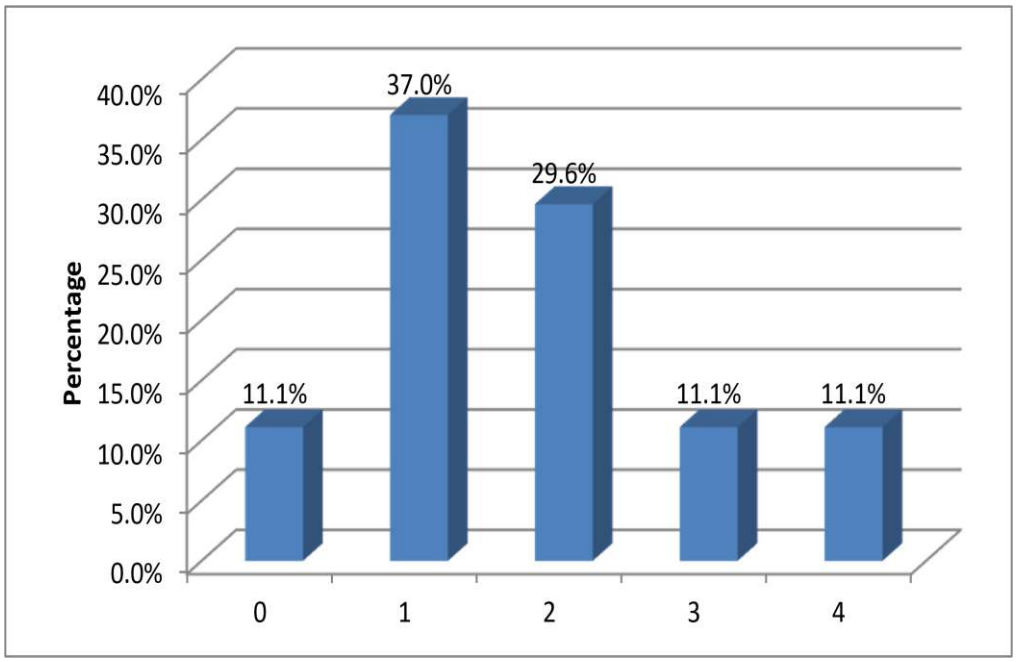

Figure 5: Showing number of additional major procedures performed in patients with infected non-union tibia.

Table 10: Showing number of minor procedures performed in patients with infected non-union tibia.

MINOR	No. of cases	Percentage
0	1	3.7%
1	9	33.3%
2	3	11.1%
3	9	33.3%
4	3	11.1%
6	2	7.4%
Total	27	100.0%

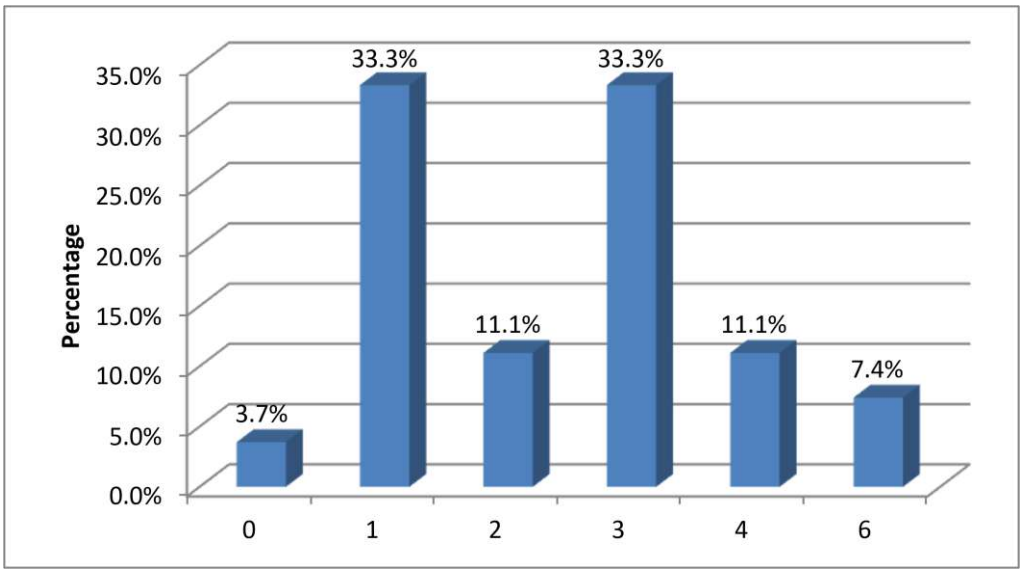

Figure 6: Showing number of minor procedures performed in patients with infected non-union tibia.

Major procedures: frame reapplication, bone grafting, flap, corticotomy.

Minor procedures: debridement, antibiotic spacer removal, wire change, readjustment, split skin grafting.

Major additional procedures for 27 patients were 1.74 on an average and every patient underwent 2.66 procedures on an average.

Table 11: Bone transport (in centimetres) in patients of infected non-union tibia.

BONE TRANSPORT(CM)	No. of cases	Percentage
2	2	7.4%
3	2	7.4%
6	2	7.4%
7	1	3.7%
8	2	7.4%
10	1	3.7%
12	2	7.4%
13	1	3.7%
14	1	3.7%
NO	13	48.1%
Total	27	100.0%

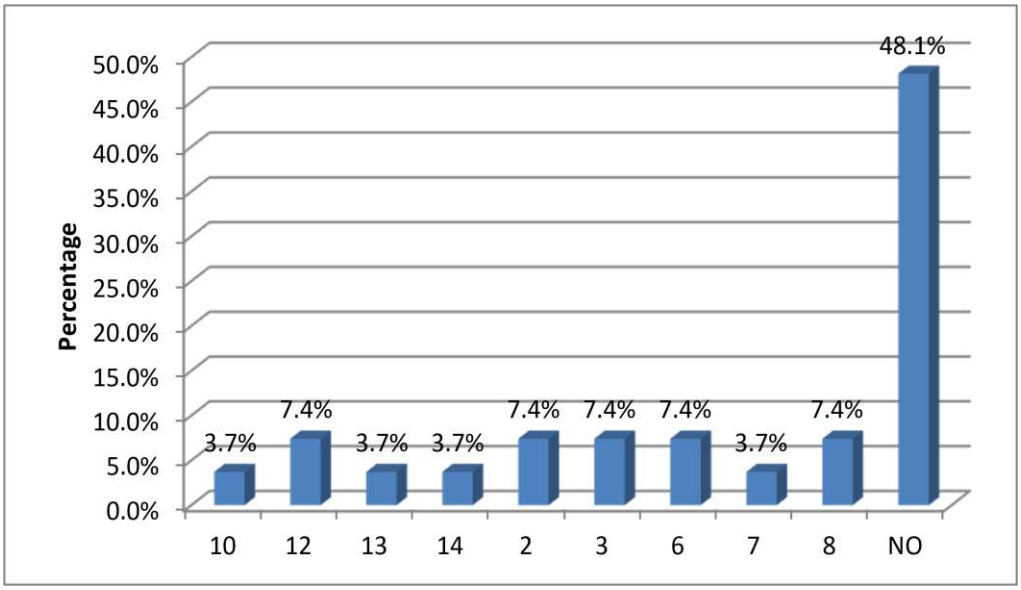

Figure 7: Figure shows number of patients who underwent bone transport.

Table 12: Showing number of patients who underwent bone grafting during the process of treatment.

BONE GRAFTING	No. of cases	Percentage
NO	7	25.9%
YES	20	74.1%
Total	27	100.0%

Out of 27 patients, 20 underwent bone grafting and 6patients were managed were compression at fracture site but one patient could not undergo bone graft due to medical issues.

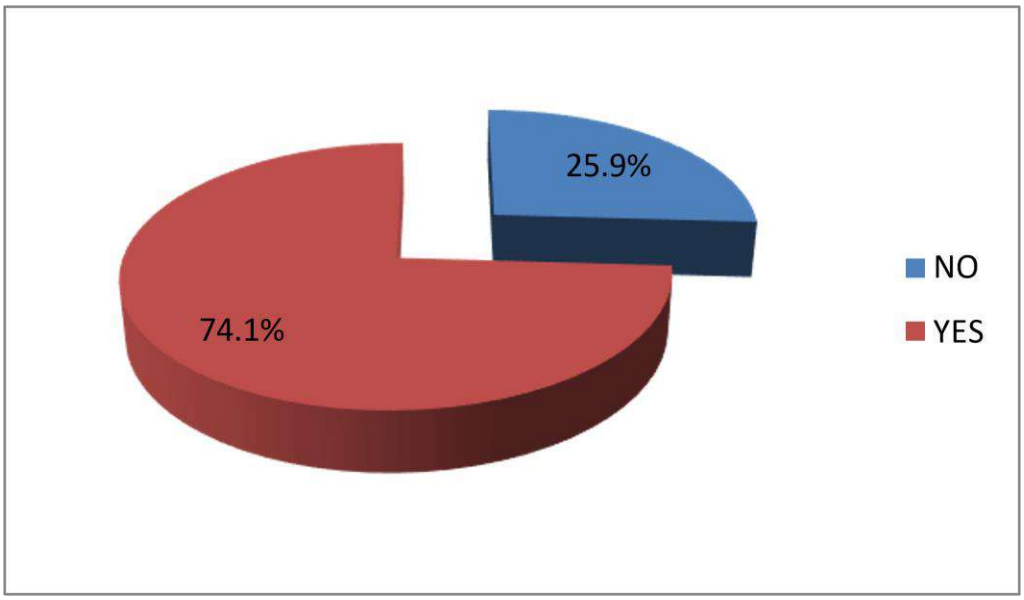

Figure 8: Figure showing number of patients who underwent bone grafting during the process of treatment.

Table 13: Showing the total time period for which patients underwent the treatment for infected non-union tibia with ilizarov fixator.

TIME PERIOD(months)	No. of cases	Percentage
6	1	3.7%
7	5	18.5%
8	1	3.7%
9	2	7.4%
10	2	7.4%
11	1	3.7%
12	3	11.1%
13	2	7.4%
15	1	3.7%
16	1	3.7%
17	1	7.4%
18	3	11.1%
25	2	7.4%
28	1	3.7%

Time for union ranges from 6 – 28 months (average 12.59)

Flow diagram showing the total time period for which patients underwent the treatment for infected non-union tibia with ilizarov fixator:

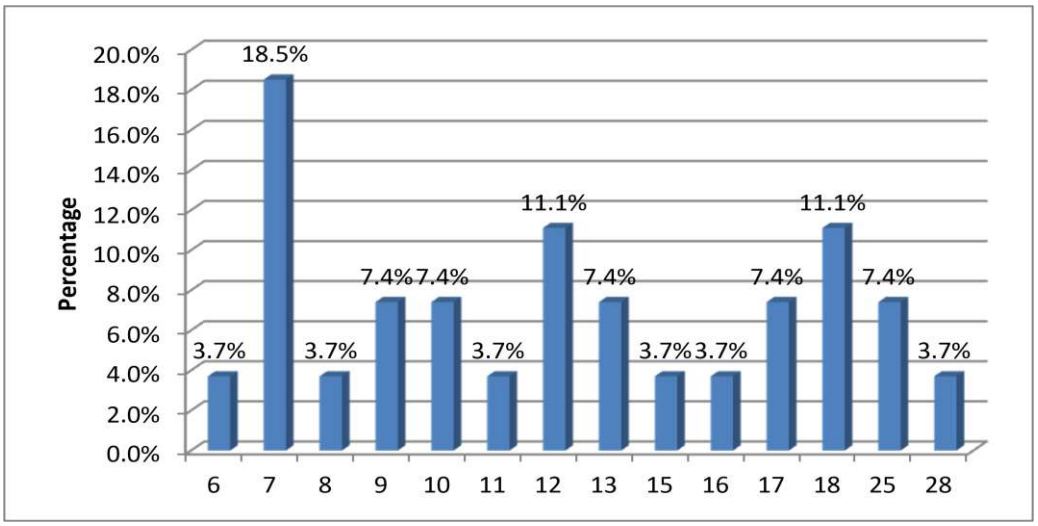

Figure 9: Showing the total time period for which patients underwent the treatment for infected non-union tibia with ilizarov fixator.

Due to application of ilizarov frame for long period of time the wire entry and 0exit sites develop pin site infection with Grade I being present in some wires in all of the patients which with gradual passage of time either resolve or progress into Grades II, III, IV.

Table 14: Showing presence of different grades of pin tract infection in patients.

PIN SITE INFECTION (MOORE DAHL GRADING)	No. of cases	Percentage
GRADE II	10	37.0%
GRADE III	6	22.2%
GRADE IV	11	40.7%
Total	27	100.0%

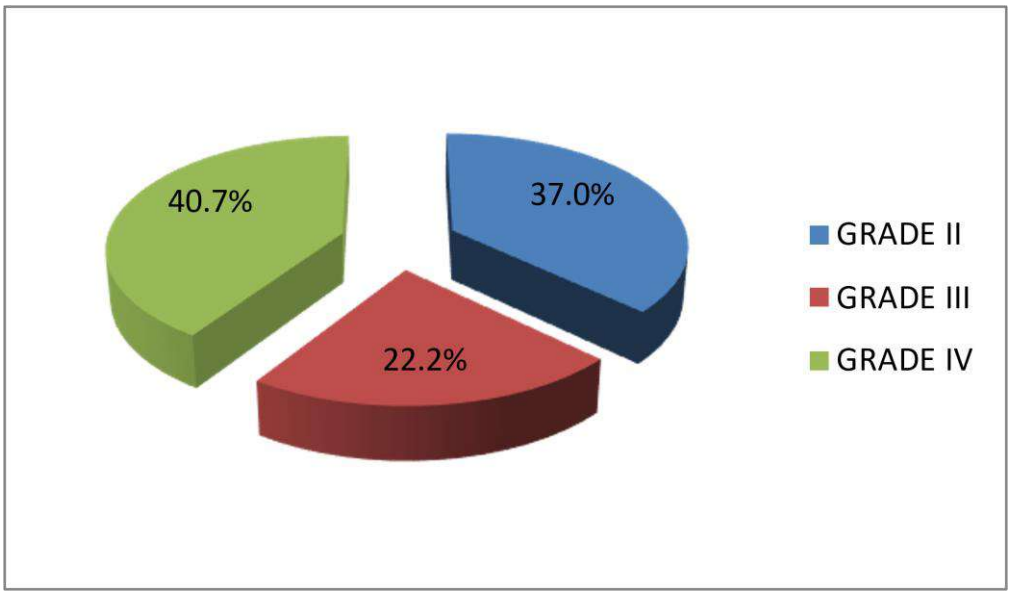

Figure 10: Figure showing presence of different grades of pin tract infection in patients.

Table 15: Showing number of patients who underwent wire change.

WIRE CHANGE	No. of cases	Percentage
DONE	11	40.7%
NO	16	59.3%
Total	27	100.0%

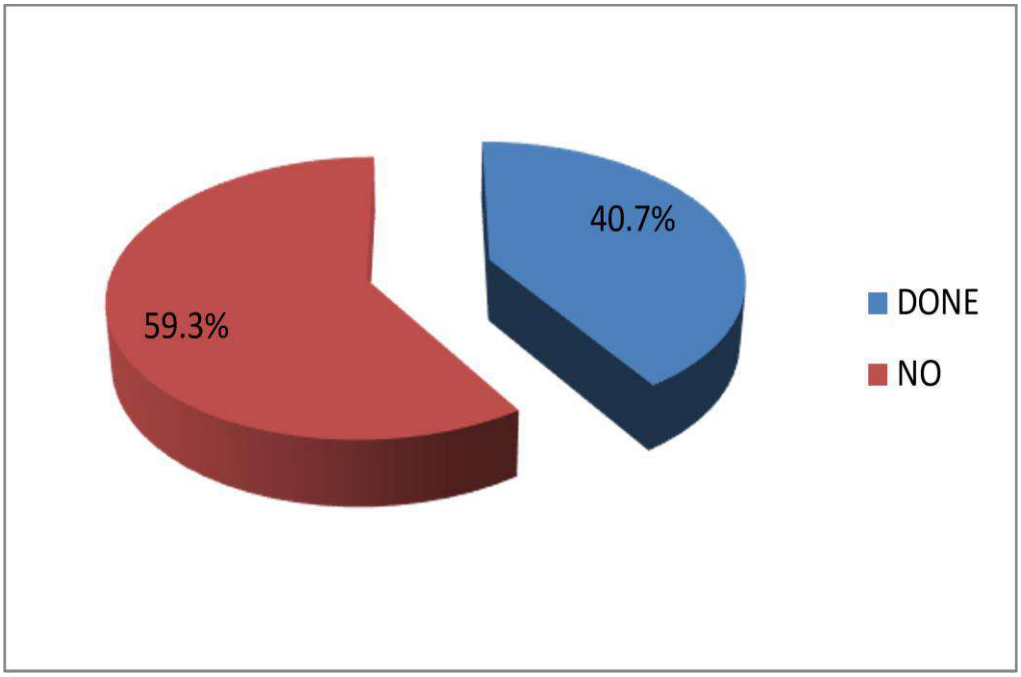

Figure 11: Showing number of patients who underwent wire change.

Table 16: Showing number of patients who underwent corticotomy.

CORTICOTOMY	No. of cases	Percentage
DONE	14	51.9%
NO	13	48.1%
Total	27	100.0%

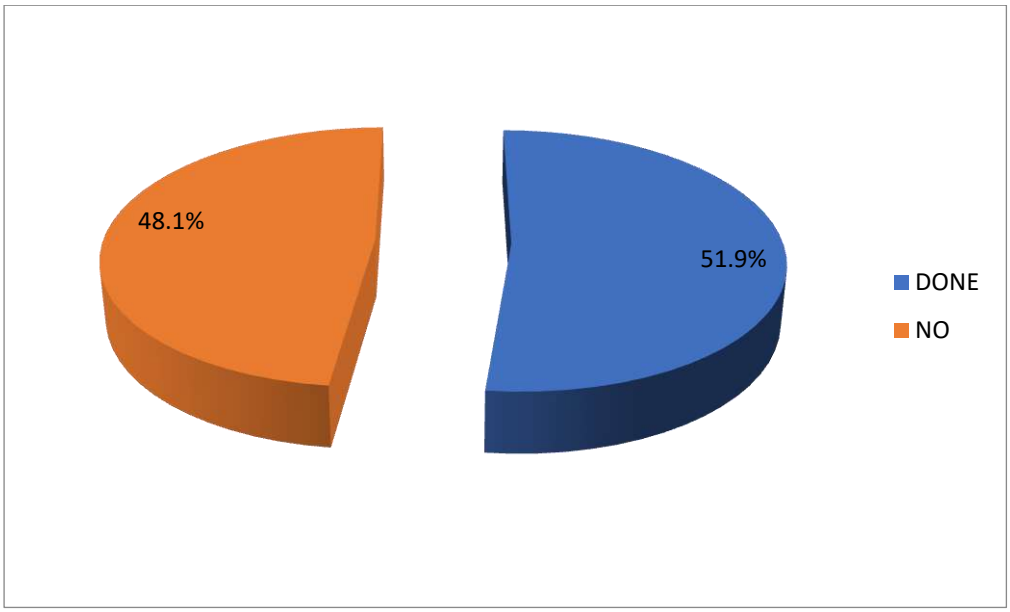

Figure 12: Flow diagram showing number of patients who underwent corticotomy.

Table 17: Showing that 26 out of 27 patients had bony union with no persistence of infection.

UNION AND ABSENCE OF INFECTION	No. of cases	Percentage
NO UNION	1	3.7%
UNION WITH NO INFECTION	26	96.3%

One patient had persistence of non-union as the patient could not undergo further interventions due medical issues.

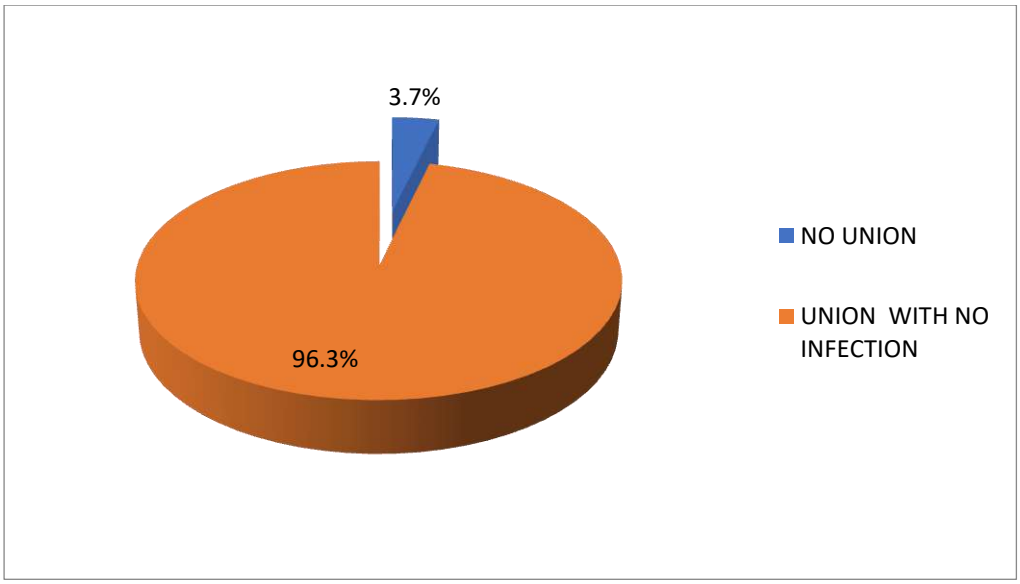

Figure 13: Showing that 26 out of 27 patients had bony union with no persistence of infection.

Table 18: Showing that out of total patients(n=27) the deformity of more than 7 degrees was present in 11 patients and less than 7 degrees in 16 patients.

DEFORMITY	No. of cases	Percentage
> 7 DEGREES	11	40.7%
< 7 DEGREES	16	59.3%
Total	27	100.0%

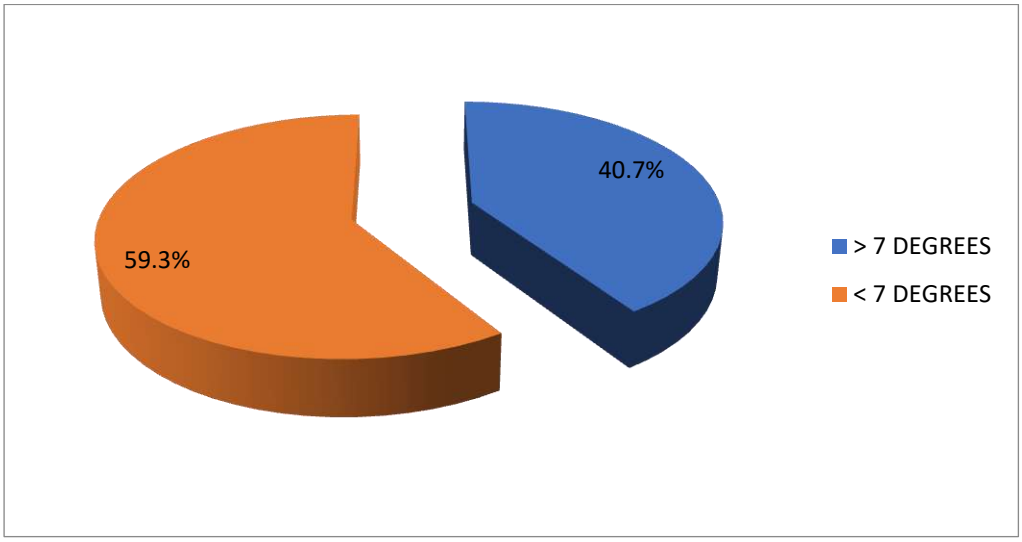

Figure 14: Showing that out of total patients (n=27) the deformity of more than 7 degrees was present in 11 patients and less than 7 degrees in 16 patients.

In our study all the patients had limb length discrepancy of less than 2.5cms.

Table 19: Showing bone outcome in patients with infected non-union fracture tibia according to ASAMI Score.

BONE RESULTS	No. of cases	Percentage
EXCELLENT	16	59.3%
GOOD	10	37.0%
POOR	1	3.7%
Total	27	100.0%

Union was achieved in 26 patients out of 27. One patient did not achieve union and any further intervention could not be carried out due to medical issues.

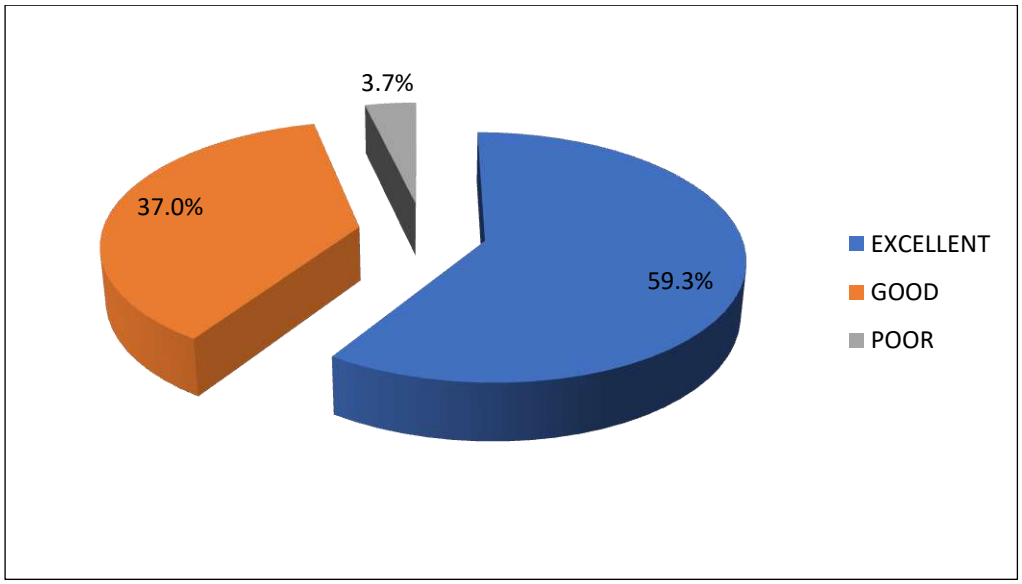

Figure 15: Figure showing bone outcome in patients with infected non-union fracture tibia according to ASAMI Score.

The problems observed after functional assessment were-

Table 20: Showing that out of 27 patients 10 patients had a noteworthy limp.

LIMP	No. of cases	Percentage
ABSENT	17	63.0%
PRESENT	10	37.0%
Total	27	100.0%

Table 21: Knee stiffness.

KNEE RANGE OF MOTION	No. of cases	Percentage
100	2	7.4%
110	8	29.6%
130	17	63.0%
Total	27	100.0%

Distribution of participants in terms of knee stiffness(n=27) shows varying degrees of knee stiffness in patients with 8 patients having slight stiffness and 2 patients with knee range of motion up to 100 degrees.

Table 22: Ankle stiffness(n=27).

ANKLE DORSIFLEION	No. of cases	Percentage
10	12	44.4%
20	15	55.6%
Total	27	100.0%

In this study out of total 27 patients 12 had limited dorsiflexion with four patients having stiff ankle.

Table 23: Complication of pain.

PAIN	No. of cases	Percentage
ABSENT	22	81.5%
PRESENT	5	18.5%
Total	27	100.0%

Distribution in terms of patients having pain(n=27) shows that out of 26 patients only 5 of the patients experienced pain.

Table 24: Functional outcome according to Association of Surgeons for the Application and Methodology of Ilizarov (ASAMI) score.

OUTCOME	No. of cases	Percentage
EXCELLENT	7	25.9%
FAIR	4	14.8%
GOOD	14	51.9%
POOR	2	7.4%
Total	27	100.0%

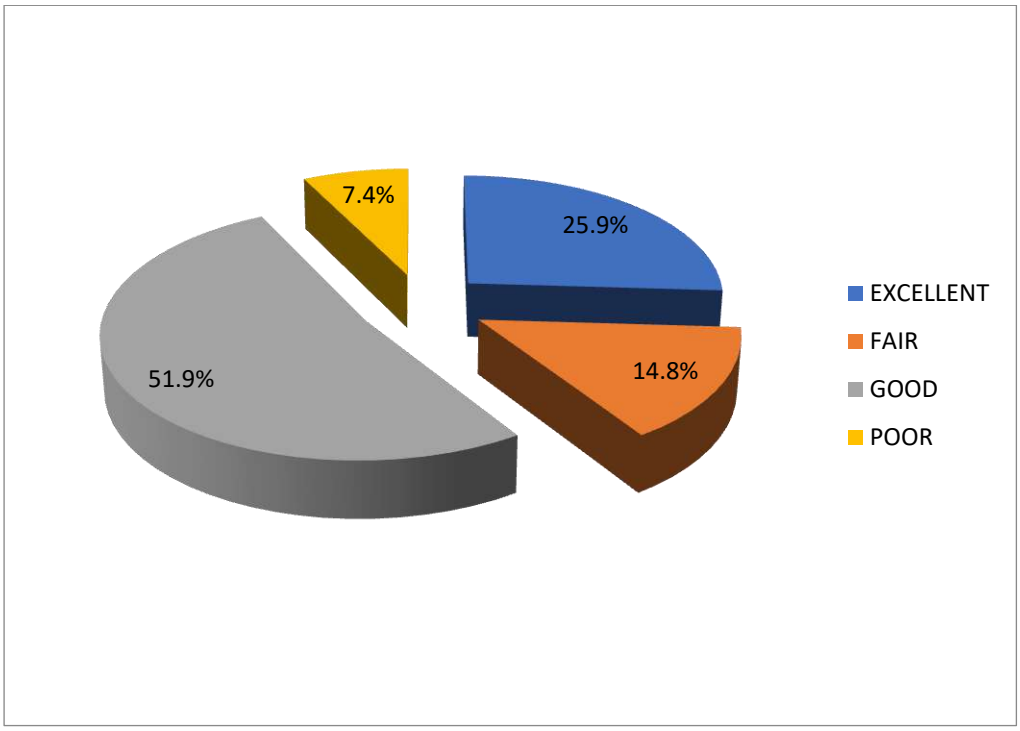

Figure 16: Functional outcome.

In this study functional outcomes were recorded in 27 patients according to ASAMI score. Out of 27 patients 25.9 % were excellent, 51.9 % were good, 14.8 % were fair and 7.4 % were poor.

DISCUSSION

In developing countries, the majority of the bulk is the working population, and the long distances traveled to the workplace compounded by critical transport demands, increases the risk of road traffic accidents. These patients are often young, active, and bread earners of their families. Infected tibia non-union is common in clinical practice, and there are usually some coexisting problems of bone and soft tissue loss, deformities, limb length inequalities, and poly-bacterial infection. The treatment of infected tibial non-union has still been a challenge for all orthopedic surgeons. Ilizarov method has gained popularity for the treatment of infected non-union

Its treatment necessitates appropriate planning and execution to derive optimal outcomes. For a long, ilizarov ring fixation is being used for the treatment of non-union of bones and is especially used in infected non-union of the tibia. Distraction histogenesis is the principle used here in non-union. The ilizarov ring fixator enables stabilization even after resection of the infected bone; joint movement and functional loading can be started within the first few days after the application of the fixator to minimize loss of working hours and income associated with staged procedures and prolonged recovery. In order to further demonstrate the effectiveness of ilizarov methods and give a better guideline for clinical treatment of infected non-union, we conducted this study of functional outcomes of infected non-union fracture tibia treated by the ilizarov fixator.

In this study, all patients had infected non-union of the shaft of the tibia due to either compound wound or infection followed by the primary fixation. Patients with infected wounds and soft tissue and bone loss were treated with flap cover and corticotomy with distraction or bone grafting done accordingly. Our success in the eradication of chronic infection, with no recurrences after follow-up is very satisfactory. Some required excision of a segment of bone which was then regrown from regions of good vascularity.

Age and Sex: The mode of injury was workplace injury and mostly roadside accidents where there was a predominance of the younger age group (average age 44.1 years; range 15-70 years.)

Table 25: Average age of participants in different studies.

Study	AVERAGE AGE	RANGE
Current study	44.1YEARS	20-69 YEARS
Meleppuram et al	38 YEARS	26-64 YEARS
Mankar et al	43.5 YEARS	7-65 YEARS
Sreeram et al	39.3 YEARS	30-50 YEARS

The higher incidence in the younger population corresponds closely with the increased rate of road traffic accidents at this age.

In this study out of all 27 patients 23 were male and 4 were female patients.

Conventionally many methods were employed to overcome the problem of infected gap non-union in the tibia, but all of them have several shortcomings and limitations. Multiple debridements, sensitivity-guided antibiotics, irrigation of the wound, and vacuum-assisted closure with topical antibiotic delivery systems have all been used to eradicate infection.

In terms of an organism, patients grew different organisms like staphylococcus aureus, pseudomonas, klebsiella, etc and some patients had negative cultures as they were on antibiotics preoperatively.

In all of the 27 patients after all the procedures and antibiotics the infection resolved and radiological and clinical signs of resolution of infections were seen.

In 26 out of 27 patients bony union was seen with ilizarov fixator and additional protection with a brace was given for 6-12 weeks and in one patient did not achieve union and further intervention could not be carried out due to medical issues.

Table 26: Bone results were graded according to the ASAMI score.

Bone outcomes	**Current study**	**Meleppuram et a(%)**	**Mankar et al(%)**	**Sreeram et al(%)**
Excellent	59.3	60	72.2	70
Good	37	15	11.1	20
Fair	-	25	16.7	5
Poor	3.7	-	-	5

Figure 17: Xray image showing excellent bone results.

Meleppuram et al (2015) retrospectively analyzed 42 patients with infected tibial non-union with bone loss; shortening and deformity treated with ilizarov ring fixator. The bone results of the study were excellent in 60% of patients, good in 15%, fair in 25%, and poor in 0%.[62]

Sreeram et al(2014) studied 20 patients admitted and treated with ilizarov fixator for infected non-union of long bones and the bone results were excellent in 70% of patients, good in 20%, fair in 5%, and poor in 5%.[61]

Mankar et al (2018) did a retrospective study in 18 patients who were treated with an ilizarov external fixator for infected non-union of the tibia. The bone results as assessed with the ASAMI outcome score were excellent in 72.2%, good in 11.1%, and poor in 16.7%.[55]

Table 27: Functional results were graded according to ASAMI criteria.

Functional outcomes	**Current study**	**Meleppuram et a(%)**	**Mankar et al(%)**	**Sreeram et al(%)**
Excellent	25.9	55	50	50
Good	51.9	30	33.3	40
Fair	14.8	5	-	5
Poor	7.4	10	16.7	5

In this study retrospective and prospective analysis of 27 patients with infected non-union of fracture tibia treated with ilizarov external fixator was done and functional results according to ASAMI score were seen as 25.9 % were excellent,51.9 % were good,14.8 % were fair and 7.4 % were poor.

Meleppuramet al(2015) retrospectively analyzed 42 patients with infected tibial non-union with bone loss; shortening and deformity treated with ilizarov ring fixator. The functional results of the study were excellent in 55% of patients, good in 30%, fair in 5%, and poor in 10%.

Sreeram et al, (2014) studied 20 patients admitted and treated with ilizarov fixator for infected non-union of long bones and the functional results were excellent in 50% of patients, good in 40%, fair in 5%, and

poor in 5%.

Mankar et al (2018) did a retrospective study in 18 patients who were treated with an ilizarov external fixator for infected non-union of the tibia. The function results as assessed with the ASAMI outcome score were excellent in 50%, good in 33.3%, and poor in 16.7%.

Figure 18: Excellent functional results in a patient with an infected non-union tibia managed with an ilizarov fixator and undergone bone transport.

Complications

Pin tract infection:

In our study there were a few complications of the ilizarov ring fixator with most common being the pin tract infection. We classified pin tract infection according to Moor and Dahl classification. Grade I infection was present in all of the patients in one or more wires. In 10 patients these progressed to grade II, grade III in 6 patients and grade IV was observed in 11 patients which were managed and cured completely with multidisciplinary approach with tobramycin drops at pin tract and pin tract care and intravenous antibiotics if required the change of wire was done in 11 patients which is reflected in additional procedures in our series. Our average time of union is 12 months, therefore pin site infection were inevitable despite a very strict protocol for pin site care.

In the study of Sreeram et al pin track infections (grade I & grade II) were seen in 10 patients out of 20 patients and all of them were cured with a course of antibiotics and pin tract care.

In the study by Meleppuram et al, the problems consisted mainly of pin tract infection in 30 patients assessed by Moore and Dahl grading of which 16 patients had Grade II infection, 12 patients had grade III infection and two had Grade IV infection. These subsided with regular dressings and oral antibiotics. Five patients with pin tract infections were resolved by intravenous antibiotics.

Mankar et al found pin-tract infection in six patients which was managed with oral antibiotics and local tract care with iodine application.

Knee and ankle contractures:

All the patients who underwent distraction osteogenesis had distal very high chances of joint stiffness and contractures because the muscles respond poorly to the distraction rate of 1mm/day and as the gastrosoleus forms the main bulk in the calf, it resulted and can result

in ankle joint stiffness. The stiffness was overcome to some extent by regular physiotherapy. The gait training was started with a crutched/walker in the early postoperative period (24-72 hours) except where other injuries did not allow mobilization and intensive physiotherapy was started to prevent joint contractures. An elastic band was used to prevent ankle deformity. After all these measures still there a few patients that had a slight decrease in ankle dorsiflexion and knee flexion contractures.

Table 28: Patients with Ankle stiffness.

Ankle dorsiflexion	**No. Of cases**	**Percentage**
10	12	44.4%
20	15	55.6%
Total	27	100.0%

Table 29: Patients with Knee stiffness

Knee range of motion	**No. Of cases**	**Percentage**
100	2	7.4%
110	8	29.6%
130	17	63%
Total	27	100.0%

Sreeram et al observed that out of 20 patients, 11 showed loss of ankle dorsiflexion of more than 15 degrees after the frame removal. After physiotherapy, 5 gained a useful range of movement. One patient had fixed equinus deformity, one patient complained of knee stiffness and none of the patients had a loss of extension more than 15 degrees.

In the study by Mankar et al limb length discrepancy was less than 2.5 cm in 50% of the cases and more than 2.5cm in only one patient, and the rest could achieve almost normal length. The deformity was less than 7 degrees in less than 20% of the cases and 15 % has limp, 10 %had pain and 5% had limb stiffness.

Table 30: Shows patients with limp.

Limp	No. Of cases	Percentage
Absent	17	63 %
Present	10	37 %
Total	27	100.0%

Table 31: Shows patients with pain.

Pain	No. of cases	Percentage
Absent	22	81.5%
Present	5	18.5%
Total	27	100.0%

The discrepancy was mostly less than 2.5 cm in 10 patients and less than 1 cm in 17 patients who were treated by heel raise in shoes and the pain usually went away with gradual physiotherapy and analgesics and no major cause of pain like infection, or refracture was seen.

Fortunately, in our study, sympathetic dystrophy was not observed in any of the patients.

SUMMARY AND CONCLUSION

Tibia fractures with or without bone gaps are becoming increasingly common due to high-speed road traffic accidents and often present a challenge in reconstruction. The low vascularity of the leg in general and the accompanying soft tissue loss often with exposed and de-vascularised bone provides a fertile bed for infection. Even if the bone gap is not present initially, a significant bone gap results as radical debridement forms an essential pillar of successful treatment to eradicate the infection.

Distraction osteogenesis and bone transport can be considered to be the gold standard for infected gap non-union of the tibia as it simultaneously solves the problem of the bone gap, infection (radical debridement without fear of bone gap) deformity correction, early weight bearing, and concomitant soft tissue expansion. It requires meticulous attention to surgery and post-operative care along with good patient counseling on the part of the surgeon. It also requires a great deal of cooperation for a long duration of time on the part of both the surgeon and the patient.

Overall ilizarov bone transport is an effective salvage tool in obtaining union in patients with an infected non-union associated with bone loss. The lengthy treatment time and a considerable number of complications must be fully understood both by the surgeon and the patient before undertaking this unique treatment process.

The present study comprised twenty-seven patients with infected non-union of the tibia {24 males: 3 females} treated with ilizarov ring fixator where bone and functional results were measured according to ASAMI score and functional results were found to be 25.9 % as excellent,51.9 % as good,14.8 % as fair and 7.4 % as poor. The most common complication encountered was pin tract infection which was treated accordingly.

In conclusion, our study and the current evidence suggest that ilizarov helps in the treatment of infected non-union of the tibia with satisfied functional outcomes.

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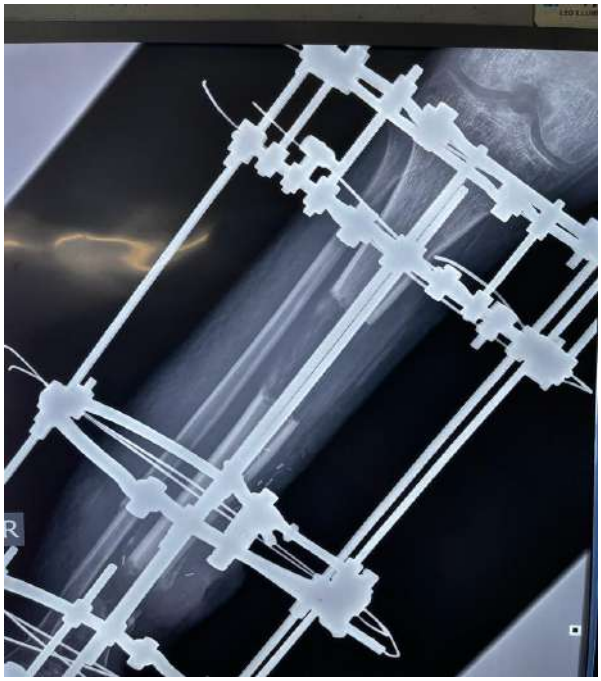
Picture 1: Pre-operative AP & lateral view

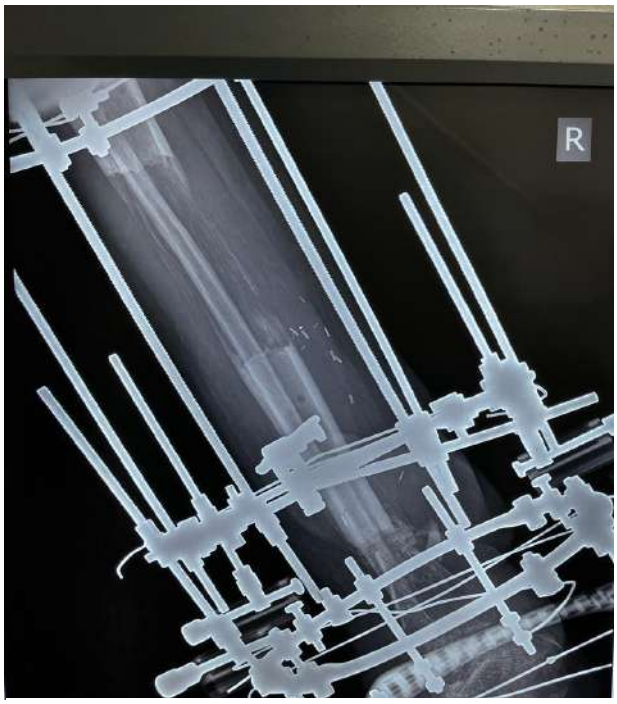
Picture 2: Post insertion of antibiotic cement spacer

Picture 3: Post corticotomy

Picture 4: Follow up during bone transport



Picture 5: Follow up post three months of bone transport



Picture 6: Follow up post six months of bone transport

Picture 7: Nine Months of bone transport

Picture 8: Post twelve months of bone transport

Picture 9: Post removal of ilizarov ring fixator

S. NO	MRD NO	ADMISSION NO	NAME	AGE	SEX	DATE OF ADMISSION	RELIGION	Date of injury	Mode of injury	FRACTURE SITE	Investigations							Diagnosis: (Using Dror Paley classification)
											HB	TLC	PLT	ESR	CRP (QUANTITATIVE)	CULTURE	Plain x-ray Ap and lateral view of the Affected limb	
1	414841	39612	CL	47	M	1/10/2018	HINDU	1/10/2018	RSA	MID TIBIA	11.9	13.2	700	43	8.5	STAPHYLOCOCCOS AUREUS	YES	C
2	612536	76508	SK	37	M	11/16/2018	HINDU	11/16/2018	RSA	MID TIBIA	14	7	215	33	9	STAPHYLOCOCCUS AUREUS	YES	C
3	530553	46712	MS	26	M	7/17/2018	SIKH	7/17/2018	RSA	MID TIBIA	12	13.3	117	66	15	E COLI	YES	C
4	595185	20674	GS	30	M	10/24/2018	SIKH	10/28/2018	RSA	MID TIBIA	12.8	10.6	183	12	3.5	NO GROWTH	YES	C
5	637603	53707	BD	68	M	5/31/2019	HINDU	5/31/2019	RSA	MID TIBIA	10.1	10	199	24	35	NO GROWTH	YES	C
6	702008	22133	DS	69	M	4/3/2019	SIKH	4/3/2019	RSA	MID TIBIA	7.8	11.3	120	68	14.9	KLEBSIELLA SPECIES	YES	C
7	727144	31658	AK	66	M	5/13/2019	HINDU	5/13/2019	RSA	DISTAL TIBIA	11.3	10.5	93	68	12	NO GROWTH	YES	C
8	267482	25433	SS	35	M	5/17/2018	SIKH	5/17/2018	RSA	DISTAL TIBIA	10.4	23	121	35	13.9	KLEBSIELLA PNUEMONAE	YES	C
9	600078	66582	AS	69	M	10/11/2018	SIKH	10/11/2018	RSA	DISTAL TIBIA	11	13.6	316	44	12	NO GROWTH	YES	C
10	759706	44535	JS	20	M	7/2/2019	HINDU	7/2/2019	WORK PLACE INJURY	PROXIMAL TIBIA	9	7.1	91	46	8.1	NO GROWTH	YES	C
11	814539	65843	R	38	M	9/20/2019	SIKH	9/20/2019	RSA	PROXIMAL AND DISTAL TIBIA	8.1	12.6	800	62	47.6	STENOTROPHOMONAS	YES	C
12	822051	78580	L	20	M	11/5/2019	SIKH	11/5/2019	RSA	PROXIMAL TIBIA	10.8	9.4	384	67	43	NO GROWTH	YES	C
13	720699	29213	BK	56	F	5/2/2019	SIKH	5/2/2019	RSA	PROXIMAL TIBIA	11.3	9.7	374	49	4	PSEUDOMONAS SPECIES	YES	C
14	844315	78904	R	40	F	11/6/2019	HINDU	11/6/2019	RSA	DISTAL TIBIA	11.2	7.9	168	35	9	E COLI	YES	C
15	29379	9525	V	48	M	6/17/2018	HINDU	6/17/2018	RSA	DISTAL TIBIA	11.1	4.5	70	58	66.7	AEROMONAS HYDROPHILLIA	YES	C
16	486211	25566	J	56	M	4/24/2018	SIKH	4/24/2018	RSA	PROXIMAL TIBIA	13.4	14	313	39	15.7	NO GROWTH	YES	C
17	585833	43881	A	21	M	9/22/2018	HINDU	9/22/2018	RSA	PROXIMAL TIBIA	12.6	8.4	354	71	25	ENTEROBECTOR CLOACAE	YES	C
18	845810	79639	V	38	M	11/8/2019	HINDU	11/8/2019	RSA	DISTAL TIBIA	10	10.6	381	74	17.9	KLEBSIELLA PNEUMONAE	YES	C
19	940412	33844	P	44	M	7/6/2020	HINDU	7/6/2020	RSA	MID TIBIA	11.5	13	215	48	12	CITROBECTOR SPECIES	YES	C
20	776581	58924	HL	52	M	12/8/2020	HINDU	12/8/2020	RSA	MID TIBIA	11	18.7	497	81	17.3	NO GROWTH	YES	C
21	1046678	12932	GS	26	M	3/10/2021	SIKH	3/10/2021	RSA	MID TIBIA	12.1	4.2	237	56	14	PSEUDOMONAS SPECIES	YES	C
22	1270091	15403	KS	62	M	3/15/2022	SIKH	3/15/2022	RSA	MID TIBIA	11	13	312	200	166	KLEBSIELLA SPECIES	YES	C
23	998015	21410	RT	38	M	11/22/2020	HINDU	11/22/2020	RSA	MID TIBIA	12.9	6	170	30	60	NO GROWTH	YES	C
24	1089566	20836	RK	27	F	4/19/2019	SIKH	4/21/2021	RSA	DISTAL TIBIA	11.5	11.5	218	60	11.8	NO GROWTH	YES	C
25	373313	13758	JS	49	M	7/19/2018	SIKH	7/19/2018	RSA	DISTAL TIBIA	14.2	8.1	338	51	120.3	NO GROWTH	YES	C
26	1222808	70510	BS	63	M	12/12/2021	SIKH	12/12/2021	RSA	DISTAL TIBIA	11	11.2	133	57	13.3	KLEBSIELLA PNEUMONAE	YES	C
27	1218922	77567	S	31	F	12/5/2021	HINDU	12/5/2021	RSA	DISTAL TIBIA	12	13	214	43	21	NO GROWTH	YES	C

S. NO	MRD NO	Date	PROCEDURE DETAILS		Date of fixation	BONE TRANSPORT (CM)	BONE GRAFTING	TIME PERIOD	PIN SITE INFECTION (MOORE DAHL GRADING)	WIRE CHANGE	CORTICOTOMY	UNION AND ABSENCE OF INFECTION	DEFORMITY	LIMB LENGTH INEQUALITY	BONE RESULTS	LIMP
			MAJOR	MINOR												
1	414841	7/5/2018	4	3	7/19/2019	3	YES	12	GRADE IV	DONE	YES	UNION WITH NO	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
2	612536	1/22/2019	1	3	10/30/2019	NO	YES	10	GRADE III	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
3	530553	11/12/2018	2	3	1/2/2020	8	YES	13	GRADE II	NO	YES	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	ABSENT
4	595185	3/28/2019	1	1	11/25/2019	2	YES	8	GRADE II	NO	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
5	637603	8/7/2019	2	3	1/17/2020	3	YES	16	GRADE IV	DONE	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
6	702008	6/6/2019	2	1	2/15/2020	NO	NO	17	GRADE III	NO	NO	NO UNION	>7 DEGREES	**<2.5 CENTIMETRES**	POOR	PRESENT
7	727144	6/20/2019	1	1	2/17/2020	NO	YES	17	GRADE II	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
8	267482	12/11/2018	4	3	2/7/2020	10	YES	25	GRADE IV	DONE	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
9	600078	2/7/2019	1	1	2/13/2020	NO	NO	12	GRADE IV	DONE	NO	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
10	759706	7/7/2019	1	1	2/10/2020	NO	YES	7	GRADE III	NO	NO	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
11	814539	11/5/2019	2	2	6/1/2020	NO	NO	7	GRADE II	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
12	822051	11/7/2019	1	2	11/9/2020	2	YES	12	GRADE III	NO	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	PRESENT
13	720699	7/2/2019	1	2	2/12/2020	NO	YES	7	GRADE III	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	PRESENT
14	844315	11/27/2019	3	4	5/28/2021	14	YES	18	GRADE II	NO	YES	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
15	29379	2/23/2020	3	4	8/16/2021	6	YES	18	GRADE IV	DONE	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
16	486211	6/20/2018	2	3	10/28/2020	NO	NO	28	GRADE IV	DONE	NO	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	ABSENT
17	585833	9/20/2018	1	3	6/11/2020	12	YES	25	GRADE IV	DONE	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
18	845810	6/17/2020	3	4	3/26/2021	7	YES	9	GRADE IV	DONE	YES	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
19	940412	7/8/2020	0	1	10/17/2020	6	YES	15	GRADE II	NO	YES	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
20	776581	3/23/2021	2	3	12/27/2021	NO	NO	9	GRADE IV	DONE	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
21	1046678	5/27/2021	2	6	11/26/2022	12	YES	18	GRADE IV	DONE	YES	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	ABSENT
22	1270091	5/15/2022	0	1	12/19/2022	NO	YES	7	GRADE II	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
23	998015	4/23/2021	4	3	3/22/2022	13	YES	11	GRADE III	NO	YES	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
24	1089566	4/19/2021	1	0	11/10/2021	8	YES	7	GRADE II	NO	YES	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
25	373313	6/17/2019	1	6	7/14/2022	NO	YES	13	GRADE IV	DONE	NO	UNION WITH NO INFECTION	>7 DEGREES	**<2.5 CENTIMETRES**	GOOD	PRESENT
26	1222808	2/11/2022	2	1	12/9/2022	NO	NO	10	GRADE II	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT
27	1218922	12/5/2022	0	1	6/21/2022	NO	NO	6	GRADE II	NO	NO	UNION WITH NO INFECTION	< 7 DEGREES	**<2.5 CENTIMETRES**	EXCELLENT	ABSENT

S. NO	MRD NO	KNEE RANGE OF MOTION	Functional results according to ASAMI Scoring System			
			ANKLE DORSIFLEION	REFLEX SYMPATHETIC DYSTROPHY	PAIN	OUTCOME
1	414841	130	20	ABSENT	ABSENT	EXCELLENT
2	612536	130	20	ABSENT	ABSENT	GOOD
3	530553	130	20	ABSENT	ABSENT	GOOD
4	595185	130	20	ABSENT	ABSENT	GOOD
5	637603	130	20	ABSENT	ABSENT	EXCELLENT
6	702008	100	10	ABSENT	PRESENT	POOR
7	727144	130	10	ABSENT	ABSENT	GOOD
8	267482	130	10	ABSENT	ABSENT	GOOD
9	600078	130	10	ABSENT	ABSENT	GOOD
10	759706	100	10	ABSENT	PRESENT	POOR
11	814539	110	10	ABSENT	ABSENT	GOOD
12	822051	110	20	ABSENT	ABSENT	GOOD
13	720699	110	20	ABSENT	ABSENT	GOOD
14	844315	130	10	ABSENT	PRESENT	GOOD
15	29379	130	10	ABSENT	ABSENT	EXCELLENT
16	486211	110	20	ABSENT	ABSENT	GOOD
17	585833	110	20	ABSENT	ABSENT	GOOD
18	845810	110	10	ABSENT	ABSENT	FAIR
19	940412	130	20	ABSENT	PRESENT	FAIR
20	776581	130	20	ABSENT	ABSENT	EXCELLENT
21	1046678	130	20	ABSENT	ABSENT	EXCELLENT
22	1270091	130	20	ABSENT	ABSENT	EXCELLENT
23	998015	110	20	ABSENT	ABSENT	GOOD
24	1089566	130	10	ABSENT	PRESENT	FAIR
25	373313	110	10	ABSENT	ABSENT	FAIR
26	1222808	130	10	ABSENT	ABSENT	GOOD
27	1218922	130	20	ABSENT	ABSENT	EXCELLENT

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The Principal,
DMC, Ludhiana.

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Guryodh Singh Sidhu**, a student of your college for **MS Orthopaedics** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis

Functional outcome of infected non union of fracture tibia managed with ilizarov fixator.

Supervisor
Dr. Harpal Singh Selhi
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The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

S P Singh

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

141. If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.

142. The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.

FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MASTER OF SURGERY

IN

ORTHOPAEDICS

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

MARCH 2021

DR. GURYODH SINGH SIDHU

DEPARTMENT OF ORTHOPAEDICS
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR
For the degree of	M.S. Orthopaedics
Name of the candidate	Dr. Guryodh Singh Sidhu
Supervisor	Dr. Harpal Singh Selhi, Professor, Department of Orthopaedics, DMC&H Ludhiana
Co-supervisor	Dr. Deepak Jain, Professor, Department of Orthopaedics, DMC&H Ludhiana
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction:. Fractures of tibia are very common in patients with trauma; many of them are open and complex type because of its subcutaneous position.To restore optimum function modern day management is fully focused on thorough wound debridement and tissue protection and stabilization. Ilizarov ring fixator has been used for stabilization in treating infected nonunited tibial fracturesOur study is to observe the results of ilizarov ring fixator for infected nonunited tibial fractures

Aim of Study: To analyse the functional outcome of these injuries using SF 36 score and ASAMI score

Materials & methods: This is retrospective and prospective analysis of functional outcomes in management of infected non union of fracture tibia by illizarov ring fixator conducted in patients undergoing treatment at dayanand medical college, hospital.

Clinical Significance: To restore optimum function modern day management is fully focused on thorough wound debridement and tissue protection and stabilization. We have used ilizarov ring fixator for stabilization in treating infected nonunited tibial fractures.By this study we can analyse the functional outcomes in patients with infected tibial non unions where ilizarov external fixator is being used.

Keywords: Infected Non Union,Ilizarov,Functional Outcome

(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR"** exist in the Department of Orthopaedics, DMC&H, Ludhiana and will be provided to be candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate himself under our supervision and guidance.

Supervisor

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APPROVAL PROFORMA
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Name of candidate	GURYODH SINGH SIDHU
Department	ORTHOPAEDICS
Topic of Thesis	FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR
Likely date of appearing in PG examination	MAY 2023
Date of enrollment	30 JUNE 2020
Name of Head of Department	Dr. Rajnish Garg
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Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Ramit Mahajan (Associate Professor, Gastroenterology)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)	Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)
Dr. Gurpreet S Wander (Vice Principal)	Dr. Gurpreet S Wander (Vice Principal & Professor & Head, Cardiology)
	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / No

Dr. Sandeep Puri
Chairperson
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Ethics Committee

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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2	NAME OF THE INSTITUTE	DAYANANAD MEDICAL COLLEGE AND HOSPITAL
3	COURSE OF STUDY AND SUBJECT	MASTER OF SURGERY IN ORTHOPEDICS
4	DATE OF ADMISSION OF COURSE	25 JULY 2020
5	TITLE OF THE TOPIC	FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Nonunion[1] of a fracture defined as injury of the bone with no possibility of healing without surgical intervention. The Food and drug administration defines nonunion as – “The fracture that is over 9 months old and that has not shown radiographic signs of progression toward healing for 3 consecutive months.”

There are several parameters that will help identify the infected nonunion of tibia fracture.[2]

- Exposed bone that has been devoid of vascularized periosteal coverage for more than six weeks
- Purulent drainage
- Positive bacterial culture from the depths of the wound
- Histological evidence of necrotic bone containing empty lacunae.

The open fracture is the most common cause of infected nonunion and the tibia is the most commonly involved bone in the infected nonunion. As a result of increasing trend for operative fracture surgery, infected nonunion after implant surgery has been moving higher.[3]

In, countries like india where there are poor traffic norms there are huge number of cases of high energy trauma. Fractures of tibia are very common in patients with trauma; many of them are open and complex type because of its subcutaneous position and thus delayed union and non union due to infection are some of the commonly acquired complications. The nonunion is often associated with infections, shortening, deformity, and poor condition of the skin. The deformities are also often complex and may include translation, angulation, and rotation of the components.[4]

The ununited tibial fracture compromised by infection is a difficult reconstructive problem for the surgeon and also becomes a chronic problem for the patient. Despite improvements in treatment modality the prevalence of infected non union still remains high. The treatment modality, outcome and prognosis are highly dependent on amount of soft tissue loss and injury, severity of injury, degree of communition, fragments displacement, mode of injury, amount of bone loss.

To restore optimum function modern day management is fully focused on thorough wound debridement and tissue protection and stabilization. We have used ilizarov ring fixator for stabilization in treating infected non-united tibial fractures. Ilizarov fixator is a recommended surgical procedure to correct the angular deformities, shortening and to achieve union at the infected non-union site.[5]

There are huge number of cases of infected nonunion of fracture tibia in all around world and huge number of studies on this topic but there is a limited amount of literature on this topic in india. Our study is to observe the results of ilizarov ring fixator for infected non-united tibial fractures. It is a method of minimally invasive external fixation system using small diameter transosseous ilizarov wires and pins which are tensioned and fixed to circular rings and rods. Ilizarov ring fixator provides good stable fixation in multidirectional and multi plane and it facilitate the cyclic micro motion at the fracture site for bone healing.

In infected non union of the bone, ilizarov ring fixator allows the surgeon to resect the necrotic bone segment and also be able to achieve stable fixation. Further, bone transport can be implemented to create bone regenerate to fill the gap.

6.2 REVIEW OF LITERATURE

The Food and drug administration defines nonunion as – "The fracture that is over 9 months old and that has not shown radiographic signs of progression toward healing for 3 consecutive months."

The major cause of infected non union are open fracture,internal fixation of a fracture or a sequelae of a chronic hematogenous osteomyelitis leading to pathological fracture.[6] Now a days, increasing number of infected nonunions are being observed and partly this is due to increased operative fracture care. The infected non union has various classifications and following are commonly followed:

1. Weiland's [7] (on extent of infection)-

Type 1- Bone exposed and soft tissue infection present (without osseous infection).

Type 2- Circumfrential cortical &endosteal infection present.

Type 3- Circumfrential cortical &endosteal infection with segmental bone loss present.

2. Gordon & Chiu's (on severity of underlying bone damage).[8] -

A- Tibial defect & nonunion without substantial bone loss
(< 3cm)

B- Tibial defect >3cm with intact fibula

C- Tibial defect >3cm with nonunion fibula

3.May et al [9] -

Type 1- An intact tibia & fibula that can withstand functional loads.
The skeletal involvement is unicortical & debridement can be done without any threat to skeletal integrity.

Type 2- An intact tibia with bone graft needed for structural support.

Type 3- A tibial defect </= 6cm with intact ipsilateral fibula.

Type 4- A tibial defect > 6cm with intact ipsilateral fibula.
(The defect > 6cm can not be bridged successfully by autograft alone)

Type 5- A tibial defect > 6cm & no usable fibula.

4. Dror Paley-

A1- Mobile atrophic, Bone loss <1cm

A2- A2.1- Stiff hypertrophic without deformity, bone loss <1cm

A2.2- Stiff hypertrophic with deformity, bone loss <1cm

B1- Osseous defect >1cm, length maintained

B2- Bone loss >1cm, shortening present

B3- Both osseous defect & bone loss with shortening.

Ilizarov external fixator is a minimally invasive procedure with thin wires transfixing the bone which are augmented by tapered pins attached to the circular frame. It is a versatile (correction of angulation, axial deformity, bone lengthening, bone transport) system in the hands of a surgeon.

Govindasamy et al [10] reported a retrospective analysis of 36 patients with infected non-union of tibia with bone loss, shortening and deformity treated with ilizarov external fixator. The results were evaluated. The Pin tract infections were assessed by Moore and Dahl Grading. The bony results were excellent in 65% patients, good in 20%, fair in 15% with no patients having poor results. The functional results were excellent in half of the patients, good in 25%, fair in 15%, and poor in 10%. The most common recorded complication was pin tract infection. Ilizarov ring fixator still remains an excellent treatment modality for tibial non-union as it addresses the problems associated with it.

Bone Results Using the Association for the Study and Application of Methods of Ilizarov (ASAMI) Scoring System

Bone Results

excellent	Union, no infection, deformity <7 ◦ , limb-length discrepancy <2.5 cm
good	Union + any two of the following: absence of infection, deformity <7 ◦ , limb-length discrepancy of <2.5 cm
fair	Union + only one of the following: absence of infection, deformity <7 ◦ , limb-length discrepancy of <2.5 cm
poor	Non-union/re-fracture/union + infection + deformity >7 ◦ + limb-length discrepancy >2.5 cm

Functional results according to ASAMI Scoring System

Functional results

excellent	Active, no limp, minimum stiffness (loss of <15◦ knee extension/<15◦ ankle dorsiflexion), no reflex sympathetic dystrophy, insignificant pain
good	Active with one or two of the following: Limp, stiffness, reflex sympathetic dystrophy, significant pain
fair	Active with at least three of the following: Limp, stiffness, reflex sympathetic dystrophy, significant pain
poor	Inactive (unemployment or inability to return to daily activities because of injury)
failure	Amputation

Mankar et al [11] reported a prospective analysis of a total of 20 patients who underwent Ilizarov's procedure. 18 had infected nonunion of tibia. The median consolidation time was 8 months. During the median follow-up of 2 years, 83.3% achieved complete union. The median union time was 11 months. Pin-tract infections were observed in 33.3% of the patients. The ASAMI (Association for the Study and Application of Methods of Ilizarov Scoring System was followed by authors. Bone results were excellent in 72.2%, good in 11.1% ,and poor in 16.7% . The function of the limb were excellent in half of the patients, good in 33.3%, and poor in 16.7%. Ilizarov's ring fixation is a reliable and suitable method for providing excellent bone and functional results in infected nonunion of tibia.

Cataneo et al [12] reported an analysis of 28 patients with infected non-union of the tibia. Six of these patients had hemi circumferential bone loss and were treated with bone transport following anterior hemi circumferential corticotomy. Infection was eradicated in 23 of the 28 patients. All fractures united but three had refractures at the nonunion site due to premature removal of the frame. They were successfully treated with re-corticotomy and circular fixator. No Patient required bone graft, microsurgery or skin grafting. Twenty-one had good functional rating(ASAMI) and others had fair rating.

El-Rosasy et al [13] reported an analysis of 21 patients with fractures of tibia complicated by bone and soft tissue loss out of which 11 were infected nonunions and managed by debridement , acute shortening and relengthening after corticotomy. During shortening, if the distal blood flow was compromised, compression was released to allow it to return. When the bone defect was greater than the safe limit for acute limb shortening, the limb was shortened to the safe limit and the remaining gap gradually closed at a rate of 2 mm to 3 mm per day. In their series all fractures united with well aligned limb with no deep infection.

Dendrions et al [14] reported an analysis of 28 infected nonunion of the tibia treated with Ilizarov fixator. Fourteen patients had excellent bone union, 8 were good, 1 fair and 5 poor results. Functionally seven had excellent rating. 11 good 4 fair and 4 were poor. All patients had eradication of infection. The infection was considered as quiescent - when wound was not draining for at least 3 months, active- when there was abscess or fever with continuous drainage from sinus.[15]

6.3 AIMS AND OBJECTIVES

To analyse the functional outcomes in management of infected non union in fracture tibia by illizarov external fixator

7.0 MATERIALS AND METHODS

This is a retrospective and prospective study done on patients who underwent treatment for infected nonunion of the tibia ilizarov ring fixator system. All the patients of infected nonunion tibia admitted in the Dayanand Medical College and Hospital, Ludhiana in orthopedics department were considered.

Proper history from the patient will be taken related to injury and the time lag.

Whether the patient is immunocompromised or not was documented in the case sheet.

Patient was asked about the presence of any comorbidities or substance abuse (smoking, alcohol).

Cultures will be taken whenever there was a discharge from the wound/sinus.

The patients with a discharging sinus at presentatation will be grouped as having active infection and those with at least 3months of discharging sinus initially which later became quiescent were grouped as having quiescent infections.

INVESTIGATIONS:

Hematological:

- hemogram
- renal function tests
- Erythrocyte sedimentation rate
- C reactive protein(CRP)(quantitative)
- Viral markers(rapid)
- Hba1c,FBS,PPBS (if diabetic)

Radiological:

Xrays full lenth with whole tibia with knee and ankle were done in AP and Lateral view.

SURGICAL TECHNIQUE:

The patient will undergo radical debridement with excision of all infected tissue and if required (if gap present between fracture ends) an antibiotic spacer will be inserted. This is followed by the ilizarov external fixator is applied following the standard protocol.

The second stage starts with removal of antibiotic spacer if insitu and corticotomy which can be done at initial stage after ilizarov or at the time of antibiotic spacer removal.

After this the bone transport is begun after 10-14 days at the rate of ¾ mm per day maximum upto 1 mm per day till the docking site is compressed and if required bone grafting is done. The number of days required for maturation 0f regenerated bone are double the number of days for bone transport. Patient is taught how to do pin site care at home.

In few cases the regeneration is poor, so here we use the Accordianrhythm(alternate compression and distraction) to increase the rate of regeneration.

Finally we dynamise the patient and loosen the ilizarov fixator and them remove the fixator and apply Patella tendon bearing(PTB) cast for 6 months.

ADVANTAGES:

- The modular design of the apparatus allows the frame to be custom built for each individual patient.
- The circular nature of the frame both enhances stability and evenly distributes the stress across the corticotomy and the distraction gap.
- The structure and strength of the frame allows weight bearing throughout the treatment, which is beneficial to the patient both in terms of day to day mobility and helping to build muscle strength and prevent joint stiffness.[16]
- When the frame is applied to the limb during surgery, only wires fix the bones to the rings, and no other skin incisions are made,

which reduces the risk of bleeding, infection, and damage to the surrounding soft tissues. [17]

- It stabilizes the fragments of bone to promote union when traditional methods of fixation are unable to give proper hold on the fracture fragments. It also allows significant compression in the case of non-unions. [18]

DISADVANTAGES:

- Pin site infection may occur due to inappropriate pin site care by the patient. [19](Moore and Dahl classification)

GRADE	CHARACTER
GRADE 0	Pin site is normal other than marginal erythema
GRADE I	Marginal inflammation
GRADE II	Inflamed pin site with serous discharge
GRADE III	Inflamed pin site with purulent discharge
GRADE IV	Osteolysis of near and far cortex
GRADE V	Osteolysis of near and far cortex with sequestrum

- There is a risk of neurological or vascular injury during surgery or distraction, although the surgical procedure is designed to minimize this type of injury. During limb lengthening, patients who are experiencing extreme pain or who demonstrate signs of vascular compromise may have the amount of daily distraction decreased. [20]
- Joint deformities may develop.
- Premature consolidation of the lengthening segment may occur before the desired limb length has been achieved.
- Application of ilizarov external fixator in children may lead to behavioural changes like frustration, anger and fear.

7.1 SOURCE OF DATA

This Is Retrospective And Prospective Analysis Of Functional Outcomes In Management Of Infected Non Union In Fracture Tibia By ilizarov external fixator Conducted In Patients Undergoing Treatment At Dayanand Medical College, Hospital.

7.2 METHOD OF COLLECTION OF DATA

Collection of data as per the proforma with consent from the patients admitted in the Orthopaedic department, Dayanand Medical College and Hospital.

INCLUSION CRITERIA

- Patients in the age group of above 15-70 years
- Both male and female patients
- Patients with infected non union in tibia

EXCLUSION CRITERIA

- Patients in the age group of above 15-70 years
- Both male and female patients
- Patients with infected non union in tibia
- Non union flowing pathological fracture
- Non union following congenital disorder

Duration of Study: The patients operated at Dayanand Medical College and Hospital, Ludhiana from 1 January 2018 and follow up till 30 June 2022 will be included in the study.

Outcome: This study will analyze the functional outcome if infected non-union of fracture tibia managed with ilizarov fixator.

Statistical Analysis: Data will be described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

This study requires surgical intervention in patients with infected non united fracture in Tibia

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Yes, Attached herewith

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PROFORMA

S.NO

NAME AGE/ SEX

MRD NO ADMISSION NO

DATE OF ADMISSION DATE OF DISCHARGE

RELIGION

Date of injury:

Mode of injury:

Time lag:

Investigations:

HB
TLC
PLT
ESR
CRP(QUANTITATIVE)
CULTURE

Signature of Candidate **Signature of Supervisor**

Plain x-ray Ap and lateral view of the Affected limb

Diagnosis: (Using Dror Paley classification)

Details

Date	Procedure	Day Care/IPD

Treatment:

Date of fixation:

Implants used:

Follow up: Evaluated with AP and lateral plain radiographs

Signature of Candidate **Signature of Supervisor**

FOLLOWUP (MONTHS)	1	3	6	9	12	18	24
ASAMI SCORE							
XRAYS							

Functional results according to ASAMI Scoring System

	Functional results	
excellent	Active, no limp, minimum stiffness (loss of <15◦ knee extension/<15◦ ankle dorsiflexion), no reflex sympathetic dystrophy, insignificant pain	
good	Active with one or two of the following: Limp, stiffness, reflex sympathetic dystrophy, significant pain	
fair	Active with at least three of the following: Limp, stiffness, reflex sympathetic dystrophy, significant pain	
poor	Inactive (unemployment or inability to return to daily activities because of injury)	
failure	Amputation	

Signature of Candidate

Signature of Supervisor

INFORMED PATIENT CONSENT

Date: _____

I.....D/o,W/o,S/o.....

am willing to participate in the study **"FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

PATIENT'S PARENT/GUARDIAN CONSENT FORM

Date: ____/____/____

I .....F/o, M/o ..... R/o ..... am willing to let my child participate in the study entitled Bed **"FUNCTIONAL OUTCOME OF INFECTED NON UNION OF FRACTURE TIBIA MANAGED WITH ILIZAROV FIXATOR"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason. This will not affect my treatment and investigation of my child.

_____ _____

Signature of the Witness Signature/Thumb Impression of guardian

Name: Name:

_____ _____

Signature of the Supervisor Signature of Candidate

ਮਰੀਜ ਦੇ ਮਾਤਾ/ਪਿਤਾ ਦਾ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ __/___/____

ਮੈਂ _____ ਪਿਤਾ/ਮਾਤਾ _____,

ਵਾਸੀ _____

"ਆਪਣੇ ਬੱਚੇ ਦੇ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਤੇ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈਂ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈਂ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ/ਚਾਹੁੰਦੀ ਹਾਂ ਕਿ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂੰ ਕਿਸੇ ਵੀ ਤਰ੍ਹਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀਂ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂੰ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂੰ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂੰ ਇਸ ਖੋਜ ਵਿੱਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆਂ ਹੈ ਅਤੇ ਮੈਨੂੰ ਇਹ ਯਕੀਨ ਹੈ ਕਿ ਇਹ ਖਤਰਾ ਬਹੁਤਾ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂੰ ਇਸ ਖੋਜ ਕੰਮ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ-ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈਂ ਇਸ ਖੋਜ ਕੰਮ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇਂ ਵਾਪਸ ਲੈ ਸਕਦਾ/ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਬੱਚੇ ਦੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀਂ ਹੋਵੇਗਾ।

_____
ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ
ਮਿਤੀ _____
ਪਤਾ _____

_____
ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ
ਮਿਤੀ _____
ਪਤਾ _____

_____
ਨਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____
ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ

मरीज के माता/पिता का अनुमति फार्म

तिथि ___/___/___

मैं _____ पिता/माता/_____ वासी _____, अपने बच्चे के इस शोधकार्य में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ कि स्वीकृत देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है कि यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामूली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे बच्चे के इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ गवाह के हस्ताक्षर

_____ मरीज के माता/पिता के हस्ताक्षर

तिथि _____

पता _____

_____

_____

_____ नरीक्षक के हस्ताक्षर

_____ प्रत्याक्षी के हस्ताक्षर